

**EPA Registration # 9480-16**

**Volume 1**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

Date: 8/28/2019

Subject: Efficacy Review for Project Flash Wipes, EPA Reg. No. 9480-RA  
(DP Barcode: 452095, Submission: 1032956)

From: Samantha Collins  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P) *Samantha Collins*

Thru: Kristen Willis, Branch Chief  
Product Science Branch  
Antimicrobials Division (7510P) *Kristen Willis*  
Date Signed: 8/28/2019

To: Jake McFarley / Zeno Bain  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hydrogen Peroxide .....	4.04%
<u>Other Ingredients</u> .....	95.96%
<u>Total</u> .....	100.0%

## **I BACKGROUND**

**Product Description (as packaged, as applied):** Towelette

**Submission type:** New Product

**Currently registered efficacy claim(s):** None

**Requested action(s):** Disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, sporicidal) ready to use towelette product for hard, non-porous surfaces at a 1-minute disinfectant contact time and 5-minute sporicidal contact time with a 5% organic soil load present (100% duck serum for Duck Hepatitis 8 virus and 500-µL final test suspension for disinfectants with sporicidal activity), addition of emerging viral pathogen claims.

**Documents considered in this review:**

- Letter from applicant to EPA dated March 20, 2018
- Data Matrix (EPA Form 8570-35)
- 23 efficacy studies (MRID 50828802- 50828820, 50667306, 50667310, 50667311, 50667312)
- Proposed label dated 03/15/2019
- Confidential Statement of Formula (EPA Form 8670-4) dated 03/20/2019.
- Emerging Viral Pathogen Claim letter dated March 20, 2019

## **II PROPOSED DIRECTIONS FOR USE**

### ***"DISINFECTING DIRECTIONS"***

**TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES:** If present, use a wipe to remove [gross filth] [and] [or] [heavy] [soil loads] prior to disinfecting. Unfold [a] [clean] wipe and thoroughly wet surface. Allow surface to remain wet for contact time(s) listed on the label [OR for one (1) minute[s] [OR for (60) seconds]]. [Use [additional] [enough] wipe(s) [,if needed,] to ensure [continuous] [wet contact time(s) listed on the label] [one (1) minute[s] [(60) seconds] wet contact time.]] [Repeated use of the product may be required to ensure that the surface remains wet [for contact time(s) listed on the label] [OR for one (1) minute[s] [OR for (60) seconds].] Let air dry. A potable water rinse is required for food contact surfaces. *[When TB is included on the label, add the following:]* A precleaning step is required to kill *Mycobacterium bovis* BCG (TB). These directions also apply to *Mycobacterium bovis* BCG (TB) at 69.8°F (21°C). *[If label includes cleaning claims for grease, soap scum, grime, dirt, messes, soil, add the following as the first sentence:* A precleaning step is required for [grease], [soap scum], [grime], [dirt], [messes], [soil]."]

### III STUDY SUMMARIES

<b>1.</b>	<b>MRID</b>	50828802	<b>Study Completion Date:</b>	02/19/19			
<b>Study Objective</b>		Disinfectant					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-307					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	PDI-0032-0022-A, PDI-0032-0023-A, PDI-0032-0024-A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		Glass microscope slides, 60					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	20°C	<b>RH</b>	30%
<b>Neutralizer</b>		Fluid Thioglycollate Medium (FTM)					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>2.</b>	<b>MRID</b>	50828803	<b>Study Completion Date:</b>	02/19/19			
<b>Study Objective</b>		Disinfectant					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-308					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Pseudomonas aeruginosa (ATCC 15442)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	PDI-0032-0022-A, PDI-0032-0023-A, PDI-0032-0024-A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		Glass microscope slides, 60					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	20°C	<b>RH</b>	30%
<b>Neutralizer</b>		Fluid Thioglycollate Medium (FTM)					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							



3.	MRID	50828804	Study Completion Date:	02/19/19			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac, 735-309					
Test organism(s)		Salmonella enterica (ATCC 10708)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	PDI-0032-0022-A, PDI-0032-0023-A, PDI-0032-0024-A					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass microscope slides, 60					
Test conditions		Contact time	1 minutes	Temp	20°C	RH	30%
Neutralizer		Fluid Thioglycollate Medium (FTM)					
Reviewer comments (i.e. protocol deviations and amendments.)							

4.	MRID	50828805	Study Completion Date:	02/25/19			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac, 735-321					
Test organism(s)		Multi-Drug Resistant (MDR) <i>Acinetobacter baumannii</i> (ATCC 19606)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass microscope slides, 60					
Test conditions		Contact time	1 minutes	Temp	21°C	RH	29%
Neutralizer		Fluid Thioglycollate Medium (FTM)					
Reviewer comments (i.e. protocol deviations and amendments.)							

<b>5.</b>	<b>MRID</b>	50828806	<b>Study Completion Date:</b>	02/25/19			
<b>Study Objective</b>		Disinfectant					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-322					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Extended spectrum p-lactamase (ESBL) <i>Escherichia coli</i> (ATCC BAA-196)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		Glass microscope slides, 60					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	21°C	<b>RH</b>	29%
<b>Neutralizer</b>		Fluid Thioglycollate Medium (FTM)					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>6.</b>	<b>MRID</b>	50828807	<b>Study Completion Date:</b>	02/25/19			
<b>Study Objective</b>		Disinfectant					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-323					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		Glass microscope slides, 60					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	21°C	<b>RH</b>	29%
<b>Neutralizer</b>		Fluid Thioglycollate Medium (FTM)					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

7.	MRID	50828808	Study Completion Date:	02/25/19			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac, 735-324					
Test organism(s)		NDM-1-Positive <i>Enterobacter cloacae</i> [CDC strain 1000654]					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		(ATCC BAA-2468)					
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass microscope slides, 60					
Test conditions		Contact time	1 minutes	Temp	21°C	RH	29%
Neutralizer		Fluid Thioglycollate Medium (FTM)					
Reviewer comments (i.e. protocol deviations and amendments.)							

8.	MRID	50828809	Study Completion Date:	02/25/19			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbac, 735-325					
Test organism(s)		Vancomycin Resistant <i>Enterococcus faecalis</i> (ATCC 51575)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass microscope slides, 60					
Test conditions		Contact time	1 minutes	Temp	21°C	RH	29%
Neutralizer		Fluid Thioglycollate Medium (FTM)					
Reviewer comments (i.e. protocol deviations and amendments.)							

9.	MRID	50828810	Study Completion Date:	02/19/19			
Study Objective		Disinfectant – virucidal					
Testing Lab; Lab Study ID		Microbac, 735-312					
Test organism(s)		Adenovirus Type 5, strain: Adenoid 75 (ATCC VR-5)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Indicator Cell Culture		A549 cells, ATCC CCL-185					
Test Method		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	PDI-0032-0022-A, PDI-0032-0023-A, PDI-0032-0024-A					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		Contact time	1 min	Temp	20-21°C	RH	34-38%
Neutralizer		DMEM+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
Reviewer comments (i.e. protocol deviations and amendments.)							

10.	MRID	50828811	Study Completion Date:	03/13/19			
Study Objective		Disinfectant – virucidal					
Testing Lab; Lab Study ID		Microbac, 735-326					
Test organism(s)		Rhinovirus Type 1A, Strain: 2060 (ATCC VR-1559)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Indicator Cell Culture		H1-HeLa cells, source: ATCC CRL-1958					
Test Method		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		Contact time	1 min	Temp	20°C	RH	32%
Neutralizer		RPMI+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
Reviewer comments (i.e. protocol deviations and amendments.)							



<b>11.</b>	<b>MRID</b>	50828812	<b>Study Completion Date:</b>	02/26/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-327					
<b>Test organism(s)</b>		Human Rotavirus, Strain: WA (ATCC VR-2018)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
<b>Indicator Cell Culture</b>		MA-104 cells, source: Charles River Laboratories					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b>	PDI-032-067A, PDI-032-068A					
	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3						
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	36%
<b>Neutralizer</b>		MEM+1% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>12.</b>	<b>MRID</b>	50828813	<b>Study Completion Date:</b>	03/13/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-328					
<b>Test organism(s)</b>		Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734)					
<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
<b>Indicator Cell Culture</b>		Vero cells, source: ATCC CCL-81					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b>	PDI-032-067A, PDI-032-068A					
	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3						
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	33%
<b>Neutralizer</b>		MEM+10% NCS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>13.</b>	<b>MRID</b>	50828814	<b>Study Completion Date:</b>	03/13/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-329					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68					
<b>Indicator Cell Culture</b>		MDCK cells, source: ATCC CCL-34					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	40%
<b>Neutralizer</b>		MEM+1% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>14.</b>	<b>MRID</b>	50828815	<b>Study Completion Date:</b>	03/13/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-330					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Respiratory Syncytial Virus, Strain: Long (ATCC VR-26)					
<b>Indicator Cell Culture</b>		HeLa cells, source: ATCC CCL-2					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	29%
<b>Neutralizer</b>		DMEM+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>15.</b>	<b>MRID</b>	50828816	<b>Study Completion Date:</b>	02/19/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-311					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Feline calicivirus, Strain: F9 (ATCC VR-782) as a surrogate for Norovirus					
<b>Indicator Cell Culture</b>		CrFK, ATCC CCL-94					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-022A, PDI-032-023A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	21°C	<b>RH</b>	27-28%
<b>Neutralizer</b>		MEM+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>16.</b>	<b>MRID</b>	50828817	<b>Study Completion Date:</b>	03/13/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-331					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Duck Hepatitis 8 Virus, Strain: Grimaud as a surrogate for Human Hepatitis 8 Virus					
<b>Indicator Cell Culture</b>		Primary Duck Hepatocytes					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	28-29%
<b>Neutralizer</b>		L-15 complete+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>17.</b>	<b>MRID</b>	50828818	<b>Study Completion Date:</b>	03/13/19			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-332					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Human Immunodeficiency Virus Type 1, Strain: IIIB, ZeptoMetrix					
<b>Indicator Cell Culture</b>		08166 cells					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	<b>Preparation</b>	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	29%
<b>Neutralizer</b>		RPMI+10% FBS+3% HEPES+ 1%NaHCO <sub>3</sub> + 0.5% Polysorbate80+0.5% Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> + 0.1% Catalase +0.025N NaOH					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>18.</b>	<b>MRID</b>	50828819	<b>Study Completion Date:</b>	03/14/19			
<b>Study Objective</b>		Disinfectant- tuberculocidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-310					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Mycobacterium bovis (ATCC 35743)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-0032-0022-A, PDI-0032-0024-A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum (heat inactivated)					
<b>Carrier type, # per lot</b>		Glass slides, 10					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	20°C	<b>RH</b>	36%
<b>Neutralizer</b>		Heat-inactivated Horse Serum					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							



19.	MRID	50828820	Study Completion Date:	02/25/19			
Study Objective		Disinfectant- mold/mildewcidal					
Testing Lab; Lab Study ID		Microbac, 735-333					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Candida albicans (ATCC 10231)					
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection <i>Additional Organism Candida albicans</i>					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-032-067A, PDI-032-068A					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum (heat inactivated)					
Carrier type, # per lot		Glass slides, 10					
Test conditions		Contact time	1 minutes	Temp	21°C	RH	29%
Neutralizer		Fluid Thioglycollate Medium					
Reviewer comments (i.e. protocol deviations and amendments.)							

20.	MRID	50667306	Study Completion Date:	04/26/2017			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Microbiotest, 735-198					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Carbapenem-Resistant Klebsiella pneumoniae, ATCC BAA-1705					
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection					
Application Method		Towelette					
Test Substance Preparation	Name/ID	Project Flash Wipes					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-0061-LO-938-146-A, PDI-0061-LO-938-146-B					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass microscope slides, 10					
Test conditions		Contact time	1 minutes	Temp	20°C	RH	30-32%
Neutralizer		Fluid Thioglycollate Medium (FTM)					
Reviewer comments (i.e. protocol deviations and amendments.)							

<b>21.</b>	<b>MRID</b>	50667310	<b>Study Completion Date:</b>	07/31/18			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-297					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Bovine Viral Diarrhea Virus, strain: NADL					
<b>Indicator Cell Culture</b>		MDBK cells, ATCG CCL-22					
<b>Test Method</b>		Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-0061-LO-1003-150-A, PDI-0061-LO-1003-151-A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per batch					
<b>Test conditions</b>		<b>Contact time</b>	1 min	<b>Temp</b>	20°C	<b>RH</b>	36.7-38.8%
<b>Neutralizer</b>		MEM+10% HS+0.5% Polysorbate80+0.3 HEPES+ 1% Na <sub>2</sub> HCO <sub>3</sub> + 0.5% NA <sub>2</sub> S <sub>2</sub> O <sub>3</sub> +0.1% Catalase					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>22.</b>	<b>MRID</b>	50667311	<b>Study Completion Date:</b>	04/26/17			
<b>Study Objective</b>		Disinfectant- Fungicidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-199					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Trichophyton mentagrophytes</i> (ATCC 9533)					
<b>Test Method</b>		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection <i>Trichophyton mentagrophytes</i>					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	PDI-0061-LO-938-146-B, PDI-0061-LO-938-146-C					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		5% fetal bovine serum (heat inactivated)					
<b>Carrier type, # per lot</b>		Glass slides, 10					
<b>Test conditions</b>		<b>Contact time</b>	1 minutes	<b>Temp</b>	21°C	<b>RH</b>	25%
<b>Neutralizer</b>		Fluid Thioglycollate Medium					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)							

<b>23.</b>	<b>MRID</b>	50667312	<b>Study Completion Date:</b>	08/01/18			
<b>Study Objective</b>		Disinfectant- Sporicidal					
<b>Testing Lab; Lab Study ID</b>		Microbac, 735-294, 735-295, 735-296					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Clostridium difficile (a toxigenic strain - tcdA-, tcdB+) (ATCC 43598)					
<b>Test Method</b>		OECD Quantitative Method for Testing Antimicrobial Products against Spores					
<b>Application Method</b>		Towelette					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Project Flash Wipes					
	<b>Lots</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	PDI-0061-LO-1003-150-A, PDI-0061-LO-1003-151-A, PDI-0061-LO-1003-152-A					
	<b>Preparation</b>	Tested concentration: LCL Dilution: RTU Diluent: N/A					
<b>Soil load</b>		500-µL: spore suspension, BSA, Mucin, YE					
<b>Carrier type, # per lot</b>		Stainless steel disks, type 304SS (test), type 430SS (controls)					
<b>Test conditions</b>		<b>Contact time</b>	5 minutes	<b>Temp</b>	21°C 22°C	<b>RH</b>	64% 48%
<b>Neutralizer</b>		Dey Engley (DE) neutralizing broth					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments.)		Gravimetric and physical wetness determination included in summary.					

#### IV STUDY RESULTS

##### Disinfection – Bactericidal Efficacy

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Mean log <sub>10</sub> Density
		Batch PDI- 0032-0022- A	Batch PDI- 0032-0023- A	Batch PDI- 0032-0024- A	
1-minute contact time, 5% soil load, RTU towelette					
50828802	<i>Staphylococcus aureus</i> (ATCC 6538)	0/60	0/60	0/60	6.0
50828803	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	0/60	5.8
50828804	<i>Salmonella enterica</i> (ATCC 10708)	0/60	0/60	0/60	5.8
		Batch PDI- 0032- 067A	Batch PDI- 0032- 068A	-	
50828805	Multi-Drug Resistant (MDR) <i>Acinetobacter baumannii</i> (ATCC 19606)	0/10	0/10	-	4.9
50828806	Extended spectrum p-lactamase (ESBL) <i>Escherichia coli</i> (ATCC BAA-196)	0/10	0/10	-	4.6
50828807	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	0/10	0/10	-	4.9
50828808	NDM-1-Positive <i>Enterobacter cloacae</i> [CDC strain 1000654] (ATCC BAA-2468)	0/10	0/10	-	4.7
50828809	Vancomycin Resistant <i>Enterococcus faecalis</i> (ATCC 51575)	0/10	0/10	-	4.8

		Batch PDI-0061-LO-938-146-A	BatchPDI-0061-LO-938-146-B	Average CFU/Carrier	
50667306	Carbapenem-Resistant Klebsiella pneumoniae, ATCC BAA-1705	0/10	0/10		$8.6 \times 10^4$

#### Disinfection – Virucidal Efficacy

Disinfection - Virucidal Efficacy						
MRID	Organism	Description	Results			Dried Virus Control (Log <sub>10</sub> TCID <sub>50</sub> /carrier)
			PDI-0032-0022-A	PDI-0032-0023-A	PDI-0032-0024-A	
1-minute contact time, 5% soil load, RTU towelette						
50828810	Adenovirus Type 5, Strain: Adenoid 75, ATCC VR-5	10 <sup>-2</sup> dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	5.11
		10 <sup>-3</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤1.80	≤1.80	≤1.80	
		Log Reduction	≥3.31	≥3.31	≥3.31	

#### Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log <sub>10</sub> TCID <sub>50</sub> /carrier)
			PDI-032-067A	PDI-032-068A	
1-minute contact time, 5% soil load, RTU towelette					
50828811	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)	10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	5.80
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.00	≥3.00	
50828812	Human Rotavirus, Strain: WA, ATCC VR-2018	10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	6.80
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤2.80	≤2.80	
		Log Reduction	≥4.00	≥4.00	
50828813	Herpes Simplex Virus Type 2, Strain: G, ATCC VR-734	10 <sup>-2</sup> dilution	Cytotoxicity	Cytotoxicity	5.80
		10 <sup>-3</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤1.80	≤1.80	
		Log Reduction	≥4.00	≥4.00	

50828814	Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68	10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	6.05
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.25	≥3.25	
50828815	Respiratory Syncytial Virus, Strain: Long, ATCC VR-26	10 <sup>-2</sup> dilution	Cytotoxicity	Cytotoxicity	5.30
		10 <sup>-3</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤1.80	≤1.80	
		Log Reduction	≥3.50	≥3.50	
50828817	Duck Hepatitis 8 Virus, Strain: Grimaud	10 <sup>-2</sup> dilution	Cytotoxicity	Cytotoxicity	4.94
		10 <sup>-3</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤1.80	≤1.80	
		Log Reduction	≥3.14	≥3.14	
50828818	Human Immunodeficiency Virus Type 1, Strain: IIIB	10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	7.10
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤4.10	≤4.10	
		Log Reduction	≥3.00	≥3.00	
			<b>PDI-0032-0022-A</b>	<b>PDI-0032-0023-A</b>	
50828816	Feline calicivirus, strain: F9, ATCC VR-782	10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	6.30
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.50	≥3.50	
			<b>PDI-0061-LO-1003-150-A</b>	<b>PDI-0061-LO-1003-151-A</b>	
50667310	Bovine Viral Diarrhea Virus, strain: NADL	10 <sup>-2</sup> to 10 <sup>-7</sup> dilution	Complete inactivation	Complete inactivation	5.57
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤0.80	≤0.80	
		Log Reduction	≥4.77	≥4.77	

**Disinfection – Tuberculocidal Efficacy, *Mycobacterium bovis* BCG (Organon Teknika)**

MRID	Lot	Medium			Carrier Control Count (Average CFU/Carrier)
		MPB	7H9	KM	
1-minute contact time, 5% soil load, RTU towelette					
50828819	PDI-0032-0022-A	0/10	0/10	0/10	5.90
	PDI-0032-0024-A	0/10	0/10	0/10	

**Disinfection – Fungicidal Efficacy**

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log <sub>10</sub> CFU/Carrier
		PDI-032-067A	PDI-032-068A	
1-minute contact time, 5% soil load, RTU towelette				
50828820	Candida albicans (ATCC 10231)	0/10	0/10	4.8
		PDI-0061-LO-938-146-B	PDI-0061-LO-938-146-C	
50667311	Trichophyton mentagrophytes, ATCC 9533	0/10	0/10	3.1 X 10 <sup>5</sup>

**Sporicidal Results – Spores of *Clostridium difficile* (ATCC 43598)**

MRID	50667312		
Spore purity	>95%		
Spore qualification	5,000 ± 250 ppm NaOCl	1,500 ± 150 ppm NaOCl	
Mean log <sub>10</sub> reduction	6.0	0.85	
Test System Control (1,500 ± 150 ppm NaOCl)	0.85		
Mean log <sub>10</sub> reduction			
Batch	PDi-0061-LO-1003-150-A	PDI-0061-LO-1003-151-A	PDI-0061-LO-1003-152-A
Test Date	05/31/18	06/07/18	06/08/18
5-minute contact time, RTU towelette, 4-part soil load			
Control Average Log <sub>10</sub> CFU/carrier	6.36	6.38	6.37
Mean Log <sub>10</sub> CFU/carrier	-0.22	-0.26	-.30
Log reduction	6.59	6.64	6.67

## V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50828802	Disinfectant, bactericidal	Hard, non-porous surfaces	RTU Towelette	1 minute	5%	N/A	• <i>Staphylococcus aureus</i> (ATCC 6538)	Yes
50828803							• <i>Pseudomonas aeruginosa</i> (ATCC 15442)	
50828804							• <i>Salmonella enterica</i> (ATCC 10708)	
50828805							• Multi-Drug Resistant (MDR) <i>Acinetobacter baumannii</i> (ATCC 19606)	
50828806							• Extended spectrum p-lactamase (ESBL) <i>Escherichia coli</i> (ATCC BAA-196)	
50828807							• Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	
50828808							• NDM-1-Positive <i>Enterobacter cloacae</i> [CDC strain 1000654] (ATCC BAA-2468)	
50828809							• Vancomycin Resistant <i>Enterococcus</i>	



50667306							<i>faecalis</i> (ATCC 51575) • Carbapenem-Resistant <i>Klebsiella pneumoniae</i> , ATCC BAA-1705	
50828810	Disinfectant, virucidal	Hard, non-porous surfaces	RTU Towelette	1-minute	5%	N/A	• Adenovirus Type 5, strain: Adenoid 75 (ATCC VR-5) • Rhinovirus Type 1A, Strain: 2060 (ATCC VR-1559) • Human Rotavirus, Strain: WA (ATCC VR-2018) • Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734) • Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68 • Respiratory Syncytial Virus, Strain: Long (ATCC VR-26) • Feline calicivirus, Strain: F9 (ATCC VR-782) as a surrogate for Norovirus • Duck Hepatitis 8 Virus, Strain: Grimaud as a surrogate for	Yes
50828811								
50828812								
50828813								
50828814								
50828815								
50828816								
50828817								

50828818							Human Hepatitis 8 Virus	
50667310							<ul style="list-style-type: none"> <li>• Human Immunodeficiency Virus Type 1, Strain: IIIB</li> <li>• Bovine Viral Diarrhea Virus, strain: NADL,</li> </ul>	
50828819	Disinfectant, tuberculocidal	Hard, non-porous surfaces	RTU Towelette	1 minute	5%	N/A	• Mycobacterium bovis (ATCC 35743)	Yes
50828820	Disinfectant, fungicidal	Hard, non-porous surfaces	RTU Towelette	1 minute	5%	N/A	<ul style="list-style-type: none"> <li>• <i>Candida albicans</i> (ATCC 10231)</li> <li>• <i>Trichophyton mentagrophytes</i> (ATCC 9533)</li> </ul>	Yes
50667312	Disinfectant, Sporicidal	Hard, non-porous surfaces	RTU Towelette	5 minutes	5%	N/A	• Clostridium difficile (a toxigenic strain - tcdA-, tcdB+) (ATCC 43598)	Yes
	Emerging Viral Pathogen	Hard, non-porous surfaces	RTU Towelette	1 minute	5%	N/A	<ul style="list-style-type: none"> <li>• Enveloped virus</li> <li>• Large, non-enveloped virus</li> <li>• Small non-enveloped virus</li> </ul>	Yes

## VI LABEL COMMENTS

**Label Date: March 15, 2019**

1. The proposed label claims that the product, Project Flash Wipes, EPA Reg. No. 9480-RA, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

*Staphylococcus aureus* (ATCC 6538)  
*Pseudomonas aeruginosa* (ATCC 15442)  
*Salmonella enterica* (ATCC 10708)  
Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)  
Extended spectrum p-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196)  
Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)  
NDM-1-Positive *Enterobacter cloacae* [CDC strain 1000654] (ATCC BAA-2468)  
Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)  
Carbapenem-Resistant *Klebsiella pneumoniae*, ATCC BAA-1705

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, Project Flash Wipes, EPA Reg. No. 9480-RA, is an effective virucidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

Adenovirus Type 5, strain: Adenoid 75 (ATCC VR-5)  
Rhinovirus Type 1A, Strain: 2060 (ATCC VR-1559)  
Human Rotavirus, Strain: WA (ATCC VR-2018)  
Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734)  
Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68  
Respiratory Syncytial Virus, Strain: Long (ATCC VR-26)  
Feline calicivirus, Strain: F9 (ATCC VR-782) as a surrogate for Norovirus  
Duck Hepatitis 8 Virus, Strain: Grimaud as a surrogate for Human Hepatitis 8 Virus  
Human Immunodeficiency Virus Type 1, Strain: IIIB  
Bovine Viral Diarrhea Virus, strain: NADL,

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the product, Project Flash Wipes, EPA Reg. No. 9480-RA, is an effective tuberculocidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

*Mycobacterium bovis* (ATCC 35743)

These claims are acceptable as they are supported by the submitted data.

4. The proposed label claims that the product, Project Flash Wipes, EPA Reg. No. 9480-RA, is an effective fungicidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

*Candida albicans* (ATCC 10231)

*Trichophyton mentagrophytes* (ATCC 9533)

These claims are acceptable as they are supported by the submitted data.

5. The proposed label claims that the product, Project Flash Wipes, EPA Reg. No. 9480-RA, is an effective disinfectant with sporicidal activity against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time:

*Clostridium difficile* (a toxigenic strain - tcdA-, tcdB+) (ATCC 43598)

These claims are acceptable as they are supported by the submitted data.

6. The proposed label claims that the product, **Project Flash Wipes**, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated **date**: March 20, 2019

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<u>One of the following:</u> Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	<u>One of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	<u>Two of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

These claims are acceptable as they are supported by the submitted data. Please remove the qualifier "one of the following" and "two of the following" as all the tested viruses have the same contact time.

7. Make the following changes to the proposed label:
- a. On page 4 of the proposed label,
    - i. Revise direction to "...remove [gross filth] [and] [or] [heavy] [soil loads]..." to "...remove visible soil loads..."
    - ii. remove the term "decontaminate" as per the 810.2100 test guidance this claim is reserved for products that are tested and proven efficacious against *B. anthracis*.
  - b. On page 6 of the proposed label,
    - i. ensure that all use sites/surfaces in the table are use sites or surfaces. For example, "Surgery" is neither a use site or surface. Revise to "surfaces in surgical center" or "Surgery Center". Similarly, revise "radiology", "physical therapy", "respiratory therapy", "anesthesia", "X-ray", "Orthopedics".
  - c. On page 10 of the proposed label,
    - i. remove the claim [ESKAPE bacteria], as not all the ESKAPE pathogens have been tested against product. Testing was conducted against *Enterococcus faecalis* and not *Enterococcus faecium*.
    - ii. remove the term "common" from claim "kills common household germs", as this statement may be false or misleading to the user.
    - iii. Remove "eradicate", "protect", "guard", "eliminate", "nosocomial", "hospital borne" and "hospital acquired" as they imply protection from disease. Please see chapter 12 of the agency Label Review Manual: <https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf>
    - iv. Remove "risk of" from the claim "Can help reduce the risk of cross contamination on treated surfaces"
    - v. Remove "daily defense against germs [or pathogens]" as it implies protection from disease.
    - vi. Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.
    - vii. Remove "completely inactivates [viruses]". The log reduction achieved may be claimed (e.g. 99.9%) however claims for complete inactivation are not acceptable.
    - viii. Revise the claim "Demonstrates 99.99% reduction of [bacteria] [insert bacteria]" to "Demonstrates 99.9% reduction of [bacteria] [insert bacteria]". The test method used to support disinfection claims is not a quantitative method. Log reduction claims are limited to 99.9%.

- ix. Remove "eliminates" from the claim "[Destroys][Deactivates][Helps] [Eliminates][Clostridium difficile...". Alternatively the claim may be revised to "eliminates 99.9999%"
- d. On page 11 of the proposed label,
  - i. remove the term "fast" as this claim is reserved for products with contact times of 30 seconds or less.
  - ii. Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.
- e. On page 12 of the proposed label, remove
  - i. "Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)" and "This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu)." This guidance has been superseded by the Emerging Viral Pathogen guidance.
  - ii. Remove the claim "Reduces exposure to microorganisms from treated surfaces" as it implies protection from disease. An acceptable alternative is "Reduces cross contamination on treated hard nonporous surfaces".
  - iii. Remove the claim "Reduces risk of infections"
  - iv. Revise the claim "This product controls the spread of germs on most hard, nonporous surfaces" to "This product reduces the spread of germs on most treated hard, nonporous surfaces"
  - v. Remove "eliminates" from the claim "[Wipes out] [kills] [Eliminates] [list organisms] in [just] [1 minutes] or [5 minutes]".
- f. On page 13 of the proposed label, remove the claim "Appropriate [perfect or great or ideal] for terminal cleaning", as this may be false or misleading to the user.
- g. On page 16 of the proposed label, remove the claim "Helps prevent cross contamination on hard, nonporous treated surfaces." Claims for prevention are not acceptable.
- h. On page 17, revise "Sporicidal" to Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

MEMORANDUM

9/25/2019

SUBJECT: Product Chemistry Review for **Project Flash Wipes** EPA Reg. No. **9480-RA**;  
DP **452031**

FROM: Sergey Alekseyev, Chemist  
Product Science Branch, CTT

Registrant: Professional Disposables  
International, Inc.

*Sergey Alekseyev*  
9/25/19

Action code: (540) New Product; Non-  
Fast Track; FIFRA Sec. 2(MM) Uses

Agency Due Date: 08/25/2019

THROUGH: Karen Hicks, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

Submission No. 1032956

E-Sub No.:

TO: Zeno Bain/Jake McFarley  
PM Team 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Formulation: EUP

Pesticide classification: bactericide,  
virucide, cleaner

MRID(s): 502825-01, 502825-02, 503566-01, and 506673-02

PC Code	CAS No.	Name	% by wt.
000595	7722-84-1	Hydrogen peroxide	4.04
		Other ingredients	95.96

THIS REVIEW CONTAINS FIFRA CBI

## I. BACKGROUND

The Registrant, **Professional Disposables International, Inc.**, has submitted a pesticide registration for their product **Project Flash Wipes**, EPA Reg. No. **9480-RA**.

## II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 – Application for Pesticide (Registration)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-34 – Certification with Respect to Citation of Data	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-27 – Formulator’s Exemption Statement	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-35 – Data Matrix, dated 03/20/2019	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter, dated 03/20/2019	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Basic and alternate # 1 CSFs, dated 03/20/2019	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Label	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Certification for Pilot Fragrance Notification Program, dated 02/14/2017	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
REFERENCED: CSF		
Comments: None.		

## III. FINDINGS

### a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

THIS REVIEW CONTAINS FIFRA CBI



Active Ingredients(s)	Nominal, %	Upper limit, %	Lower limit, %
Hydrogen peroxide	4.04	4.7	3.85
	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Wider certified limits were requested, and rationale was accepted.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. All inert ingredients are approved for food-use pesticide formulations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The impurities present >0.1% are identified.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Impurities of toxicological significance have an upper certified limit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. A toxic list 1 inert at any level	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

THIS REVIEW CONTAINS FIFRA CBI

#### **IV. Additional Findings**

1. The basic and alternate # 1 CSFs, dated 03/20/2019, are acceptable. All ingredients have been cleared for use in pesticide formulations. The certified limits for the active ingredient disagree with 40 CFR §158-350. They have been justified with the product stability.
2. MRID Nos. 502825-01, 502825-02, 503566-01, and 506673-02 contain data pertinent to all Group A and B studies exempting Oxidation/Reduction: Chemical Incompatibility, Storage Stability, and Corrosion Characteristics studies (Guidelines 830.6314, 830.6317, and 830.6320, respectively). Said studies are in progress.
3. pH and Density studies have been carried out on the liquid product Project Flash Spray, reg. no. 9480-14, composition of which is the same as impregnating component of the subject product.
4. The fragrance [REDACTED] included into the alternate # 1 CSF, has been certified for OPP Pilot Fragrance Notification program, see a letter from [REDACTED] dated 02/14/2017.
5. The towel fabric description has been included into the CSFs (see column 10) without data pertinent to their amount and certified limits. It cannot be regarded as an inert ingredient.

#### **V. Conclusion**

The registrant will satisfy the product chemistry requirements for the registration of EPA Reg. No. **9480-RA** after submission of Oxidation/Reduction: Chemical Incompatibility (Guideline 830.6314), see Additional Finding 2. Storage Stability, and Corrosion Characteristics study (Guidelines 830.6314, 830.6317, and 830.6320, respectively) should be accomplished within 1 year.

**VI. Table A:**  
**Series 830 guidelines – Group A**

OCSPP#	Name	Status	MRID
830.1550	Product Identity & Composition	Y	502825-01
830.1600	Description of materials	Y	502825-01
830.1620	Description of production process	N/A	
830.1650	Description of formulation process	Y	502825-01
830.1670	Discussion of formation of impurities	Y	502825-01
830.1700	Preliminary analysis	N/A	
830.1750	Certified limits	Y	502825-01
830.1800	Enforcement analytical method	Y	502825-01
830.1900	Submittal of samples	N/A	

**THIS REVIEW CONTAINS FIFRA CBI**

**VII. Table B: Series 830 guidelines – Group B**

OCSPP#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Colorless	Y	502825-02
830.6303	Physical state	Solid	Y	502825-02
830.6304	Odor	Mild vinegar-like odor	Y	502825-02
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI.	N/A	
830.6314	Oxidation/Reduction: Chemical Incompatibility	In progress	I	502825-02
830.6315	Flammability	No flash (<98.5 °F)	Y	502825-02
830.6316	Explosibility	The product does not contain explosive components.	W	502825-01
830.6317	Storage stability	In progress	I	502825-02
830.6319	Miscibility	The product will not be diluted with petroleum solvents.	W	502825-01
830.6320	Corrosion characteristics	In progress	I	502825-02
830.6321	Dielectric breakdown voltage	The product is not intended to be used around electrical equipment.	W	502825-02
830.7000	pH	3.71 at 25 °C	Y	502825-02
830.7050	UV/Visible absorption	Not required for MUP or EP	N/A	
830.7100	Viscosity	The product is solid.	W	
830.7200	Melting point	Not required for MUP or EP	N/A	
830.7220	Boiling point	Not required for MUP or EP	N/A	
830.7300	Density/relative	1.032 (8.60 lbs/gal) at 22 °C	Y	502825-02
830.7370	Dissociation constants in	Not required for MUP or EP	N/A	
830.7520	Particle size	Not required for MUP or EP	N/A	
830.7550/	Partition coefficient	Not required for MUP or EP	N/A	
830.7840/	Water solubility	Not required for MUP or EP	N/A	
830.7950	Vapor pressure	Not required for MUP or EP	N/A	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

**Note to PM:** 1. The inert mixture [REDACTED] contains a component with CAS No. [REDACTED] Typo error is presumed.

**THIS REVIEW CONTAINS FIFRA CBI**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 24, 2019

Jean Claude Marcelin  
Sr. Manager Regulatory Affairs  
Professional Disposables International, Inc (PDI)  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677

Subject: PRIA Regulatory Determination  
Product Name: Project Flash Wipes  
EPA File Symbol: 9480-RA  
Application Date: 03/20/2019  
Decision Number: 549617

Dear Mr. Marcelin:

The Agency has completed its review of your application and has previously communicated to you on September 10, 2019 our pre-decisional determination that identified specific label changes that were necessary in order for the Agency to approve your application. At this time, those label issues have not yet been resolved and you have not agreed to an extension to the PRIA Decision Due Date. In accordance with Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012, your application was assigned a decision review time. The Agency has reviewed the application and has determined that the pesticide "Project Flash Wipes" does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7) without the specified label changes. This determination marks the end of the PRIA decision review period. Again, EPA is attaching to this letter a marked-up copy of your label that identifies changes that must be made as well as the risk assessments that support the need for these label changes.

At this time, you have three options:

- (a) Agree to all of the terms associated with the draft accepted label as revised by the Agency and request that it be issued as the accepted final Agency-stamped label; or
- (b) Do not agree to one or more of the terms of the draft accepted label as revised by the Agency and request additional time to resolve the difference(s); or
- (c) Withdraw the application without prejudice for subsequent resubmission, but forfeit the associated registration service fee.

If you inform EPA that you have concerns as described under (b) above, you have up to 30 calendar days from the date of this letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA intends to proceed with denial of the application.

Page 2 of 2  
EPA File Symbol 9480-RA  
Decision No. 549617

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide you a stamped accepted final label within two (2) business days of receipt of your revised label.

If you have any questions, please contact Jake McFarley by phone at (703) 347-0123, or via email at [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov).

Sincerely,



Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosed: Annotated Label



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 10, 2019

Jean Claude Marcelin  
Sr. Manager Regulatory Affairs  
Professional Disposables International, Inc (PDI)  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677

Subject: Pre-Decisional Determination  
Product Name: Project Flash Wipes  
EPA File Symbol: 9480-RA  
Application Date: 03/20/2019  
Decision Number: 549617

Dear Mr. Marcelin:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.



Page 2 of 2  
EPA File Symbol 9480-RA  
Decision No. 549617

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, you may contact Jake McFarley at (703) 347-0123 or via email at [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Zeno Bain', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Attachments: Annotated Label

## PROJECT FLASH WIPES

### Alternate brand names:

Sani-Diff [™] [®] GERMICIDAL DISPOSABLE WIPE  
Sani-Cloth® Diff [™] [®] GERMICIDAL DISPOSABLE  
WIPE  
Sani-Diff HP [™] [®] GERMICIDAL DISPOSABLE WIPE  
Sani-Cloth® Diff HP [™] [®] GERMICIDAL DISPOSABLE  
WIPE  
Sani-HyPerCide [™] [®] GERMICIDAL DISPOSABLE  
WIPE  
Sani-Cloth® HyPerCide [™] [®] GERMICIDAL  
DISPOSABLE WIPE

Sani-HyPeroxide [™] [®] GERMICIDAL DISPOSABLE  
WIPE  
Sani-Cloth® HyPeroxide [™] [®] GERMICIDAL  
DISPOSABLE WIPE  
Sani-Diffex [™] [®] GERMICIDAL DISPOSABLE WIPE  
Sani-Cloth® Diffex [™] [®] GERMICIDAL DISPOSABLE  
WIPE  
Sani-DiffX [™] [®] GERMICIDAL DISPOSABLE WIPE  
Sani-Cloth® DiffX [™] [®] GERMICIDAL DISPOSABLE  
WIPE

### ACTIVE INGREDIENTS:

Hydrogen Peroxide..... 4.04%

OTHER INGREDIENTS..... 95.96%

TOTAL..... 100.00%

[Does not include the weight of the [cloth] [towelette] [or] [wipe]]

## KEEP OUT OF REACH OF CHILDREN CAUTION

See [back][outer] [carton] [side] [container[s]] [inside] [panel] for additional precautionary statements

[CONTAINS:] [or Net Contents] [and/or Net Wt.] \_\_\_\_\_oz. (g) [or lbs. (kg)]

\_\_\_\_\_ [# OF CLOTHS] [Premoistened] [Wet] WIPES [SIZE of each cloth]

EPA Reg. No.: 9480-

EPA Est. No. : 9480-NY-1

Or

EPA Est. No. A=9480-NY-1, B=72956-AR-1 [or others]

Alpha character will precede batch code on product [OR Beginning of batch code indicates Est No.]

[Manufactured by [or for]]:

Professional Disposables International, Inc. (PDI)

400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 [USA]

[For information call:] [phone number to be inserted]

[Made in [USA] [of] [with] [domestic and [foreign] [imported] materials] [insert country]]

### THE INFORMATION IN BOX IS NOT PART OF THE LABELING

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included.

A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.

When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim.

+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs\*" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2 and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 158.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

The word "and" and symbol "&" can be used interchangeably.

All directions may be written in numbered form or in paragraph form.

March 15, 2019

[On any panel]

**PRECAUTIONARY STATEMENTS:**

**Hazards to humans and domestic animals**

**CAUTION:** Causes moderate eye irritation. [1]void contact with eyes and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using [2]he [toilet] [or restroom ].

**3]IRST AID:**

[4]ontact a poison control center or healthcare professional [or doctor] for treatment advice. Have the product container or label with you when contacting a poison control center or healthcare professional [or doctor] or going for treatment. For additional information or in case of emergency contact the Poison Control Center toll free at 1-800-222-1222.

[5] in eye[s]: Hold eye[s] open, rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

**DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [See directions for use on container[s] inside.] [Consult [equipment] manufacturer's instructions prior to use.] [[For surfaces,] Test wipe on small inconspicuous area before use.]

[Use one of the following as applicable to type of container.]

[TO DISPENSE] [TOWELETTES] [or WIPES] [or TOWELS] [or CLOTHS]:

**GENERIC:**

Open lid. Pull out wipe. Close lid tightly.

**CONTAINER or CANISTER**

Remove lid [. ] [and discard inner seal] [from] [container or canister]. Find center of roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the [container or canister] lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep [center cap of] lid closed to prevent moisture loss.

**BOX:**

Open along perforations as indicated. Remove packets as needed.

**PACKET or PACKAGE:**

Tear open packet [or package]. Unfold wipe and use as directed.

[For use on small single packets only: [Not labeled for individual sale [or distribution] and/or [See dispenser [or container or box or case or outer packaging] for [additional or full label] information].

**THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.

When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim

+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

# Summary of Comments on 9480-RA-20190910 Predecisional Letter.pdf

Page: 4

---

T Number: 1 Author: jmcfarle Subject: Highlight Date: 9/6/2019 1:47:57 PM -04'00'

---

Please change to  
'Avoid contact with eyes, skin, or clothing'

---

T Number: 2 Author: jmcfarle Subject: Highlight Date: 9/6/2019 1:49:13 PM -04'00'

---

Please change to toilet.

---

T Number: 3 Author: jmcfarle Subject: Highlight Date: 9/6/2019 1:53:22 PM -04'00'

---

Please add under the 'if in eyes':

"If on skin or clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice."

---

T Number: 4 Author: jmcfarle Subject: Highlight Date: 9/6/2019 1:52:10 PM -04'00'

---

Please move this paragraph under the "if in eyes, if in skin or clothing. "

---

T Number: 5 Author: jmcfarle Subject: Highlight Date: 9/6/2019 1:51:22 PM -04'00'

---

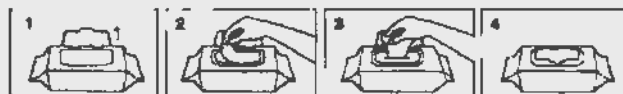
Please change:

If in eyes:

Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**[SOLO® PAK] [Portable Pack] [Soft Pack][Flow Pack][Eco-Pak]:**

Open package lid. Completely remove inner seal. Pull out wipe [at an angle] [towards you through orifice or opening]. [(The next wipe pops up automatically.)] Snap lid closed after use to retain moisture.



KEEP SOLO® LID CLOSED WHEN NOT IN USE

SOLO® is a registered trademark of Nice-Pak Products, Inc.

**REFILL [PACKET] [or PACKAGE] [or POUCH][or CANISTER][or BUCKET][or PAIL][or DISPENSER]:**

This refill package is made for use only in a [product name] container [or canister or bucket or pail or dispenser]; do not use this product in a container [or canister or bucket or pail or dispenser] for another product. Do not use the refill wipes in a container [or canister] [or bucket] [or pail][or dispenser] that is cracked or broken. Discard the cracked or broken container [or canister] [or bucket] [or pail][or dispenser] in accordance with the container [or canister][or bucket][or pail][or dispenser] disposal instructions on the label.

**[Option 1]**

Remove [entire] lid from container [or canister or bucket or pail or dispenser]. Tear open refill packet [or package] [or pouch] at notch [or mark] [or arrow] and place [wipe] roll in empty container [or canister or bucket or pail or dispenser]. Follow information on container [or canister or bucket or pail or dispenser] to dispense wipes.

**[Option 2]**

Remove [entire] lid from container [or canister or bucket or pail or dispenser]. Tear open refill packet [or package] [or pouch] at notch [or mark] [or arrow]. Place [entire] refill packet [or package] [or pouch] of wipes in empty container [or canister or bucket or pail or dispenser]. Follow information on container [or canister or bucket or pail or dispenser] to dispense wipes.

**CONTAINER [or CANISTER or BUCKET or PAIL or DISPENSER] [numbers optional]**

1. Remove [the] lid [from] [the] [pail or bucket or container or canister or dispenser].
2. [Press] open [the] [dispenser at center of [the] lid].
3. Open [the] refill [packet] [package] [pouch] then place in [pail or bucket or container or canister or dispenser].
4. Locate [the] first wipe at [the] center of [the] roll.
5. Feed [the] first wipe though [the] dispensing orifice.
6. Reapply [the] lid [to] [the] [pail or bucket or container or canister or dispenser].
7. Dispense [the] wipe.

**FOR THE REFILL[S] [PACKET] [PACKAGE] [POUCH] [or CANISTER][or BUCKET][or PAIL][or DISPENSER]:**

1. Remove [the] lid from [the] [pail or bucket or container or canister or dispenser].
2. Remove [the] empty refill [packet] [package] [pouch] material from [the] [pail or bucket or container or canister or dispenser].
3. [Press] open [the] dispenser at center of [the] lid.
4. Open [the] refill [packet] [package] [pouch] then place in [pail or bucket or container or canister or dispenser].
5. Locate [the] first wipe at [the] center of [the] roll.
6. Feed [the] first wipe though [the] dispensing orifice.
7. Reapply [the] lid [to] [the] [pail] [or bucket or container or canister or dispenser].
8. Dispense [the] wipe.

**THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

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When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim

+All pesticidal "germ" claims must be linked to bacteria (minimum, *Salmonella* and *Staph*) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills *Salmonella enterica*, *Staphylococcus aureus*, Herpes Simplex Type 2, and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

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The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

## **[1] DISINFECTING DIRECTIONS]**

**[2] O [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES:** If present, use a wipe to remove **[3] gross filth [and] [or] [heavy] [soil loads]** prior to disinfecting. **[4] nfold [a] [clean] wipe** and thoroughly wet surface. **[5] Allow surface to remain wet for contact time(s) listed on the label [OR for one (1) minute[s] [OR for (60) seconds]].** [Use [additional] [enough] wipe(s) [if needed,] to ensure [continuous] [wet contact time(s) listed on the label] **[6] one (1) minute[s] [(60) seconds] wet contact time.]]** [Repeated use of the product may be required to ensure that the surface remains **[7] wet [or contact time(s) listed on the label] [OR for one (1) minute[s] [OR for (60) seconds].]** Let air dry. A potable water rinse is required for food contact surfaces. *[When TB is included on the label, add the following:]* A precleaning step is required to kill *Mycobacterium bovis* BCG (TB). These directions also apply to *Mycobacterium bovis* BCG (TB) at 69.8°F (21°C). *[If label includes cleaning claims for grease, soap scum, grime, dirt, messes, soil, add the following as the first sentence: A precleaning step is required for [grease], [soap scum], [grime], [dirt], [messes], [soil].]*

### **[9] The following sets of directions are optional]**

**ULTRASOUND TRANSDUCERS AND PROBES:** For use on external surfaces of ultrasound transducers, scopes [and] [or] probes only prior to high-level disinfection [(HLD)].

To disinfect **[10] and decontaminate] prior to high-level disinfection [or HLD]]:** Preclean gel from external surface of ultrasound transducer, scope, [and] [or] probe[s] by using a clean washcloth or [germicidal] wipe. Then, follow instructions to disinfect.

*[The following instructions are to be included on production labels when claims against HIV, and/or HBV and/or HCV are listed; one, two or all three of the viruses may be included on claims and directions in production labels.]*

**\*KILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS [AND PRECLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [AND PROBE(S)] PREVIOUSLY SOILED WITH BLOOD/ BODILY FLUIDS** at room temperature (68°-77°F) or (20°- 25°C) in healthcare or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or bodily fluids, and in which the surfaces/objects likely to be soiled with blood or bodily fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

**\*SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON SURFACES/OBJECTS SOILED WITH BLOOD/ BODILY FLUIDS:**

**Personal protection:** When handling HIV-1 (AIDS Virus), HBV or HCV infected blood or bodily fluids; wear disposable protective gloves, protective gowns, masks and eye coverings, per facility protocol.

**Cleaning procedure:** All blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection by the [germicidal] wipe.

**Disposal of infectious materials:** Used wipe that may be contaminated with blood and other bodily fluids should be disposed of according to local regulation for infectious waste disposal.

**Contact time:** Use [germicidal] wipe to thoroughly wet surface. Allow surface to remain **[11] t for contact time(s) listed on the label [12] R for one (1) minute[s] [OR for (60) second[s]].** [Use [additional] [enough] wipe(s) [if needed,] to ensure [continuous] [wet contact time(s) listed on the label.] **[one [13] minute[s] [or (60) seconds] wet contact time.]]** [Repeated use of the product may be required to ensure that the surface remains wet [for contact time(s) listed on the label.] [for one (1) minute[s] [for (60) seconds].] Let air dry.

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Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

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March 15, 2019

## Page: 6

T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 2:29:38 PM -04'00'	Please remove brackets.
T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:52:38 AM -04'00'	remove clean. These claims should be separated from pesticidal claims.
T	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 2:39:25 PM -04'00'	please change to 'visible soils loads'.
T	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 2:30:58 PM -04'00'	Why would a wipe be folded? If the user is using a clean wipe then the wipe should not be folded. Please change this.
T	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:55:51 PM -04'00'	Must write "insert organism from under the table with 1 minute contact time." Add visibly to wet.
T	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:55:03 AM -04'00'	Change to visibly wet and Must write "insert organism from table where qualifier under the 1 minute contact time."
T	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:46:14 AM -04'00'	Change to visibly wet.
T	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:55:33 AM -04'00'	"insert organism from under the table with 1 minute contact time."
T	Number: 9	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:47:40 AM -04'00'	Must remove. Label uses can always be removed but picking and choosing directions within each category/rate/contact time is not allowed.
T	Number: 10	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 3:47:21 PM -04'00'	remove the term "decontaminate" as per the 810.2100 test guidance this claim is reserved for products that are tested and proven efficacious against <i>B. anthracis</i> .
T	Number: 11	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:49:47 AM -04'00'	change to visibly wet.
T	Number: 12	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:50:14 AM -04'00'	Remove brackets and change to 1 minute.
T	Number: 13	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 11:50:54 AM -04'00'	remove brackets and change to visibly wet.



**[The following instructions are to be included on production labels when *C.difficile* spores claims are listed.]**

**Special Instructions for Cleaning Prior to Disinfection Against *Clostridium difficile* [spores].**

**Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks and eye covering [per facility protocol].

**Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the [1]poricidal product. Cleaning is to include [vigorous] wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Waste Disposal:** Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.

**Contact time:** Use [germicidal] wipe to thoroughly wet surface. Allow surface to remain wet for contact time(s) listed on the [3]label [OR for five (5) minute[s].] [2]Use [additional] [enough] wipe(s) [if needed.] to ensure [continuous] [wet contact time(s) listed on the label.] [five (5) minute[s] wet contact time.]] [Repeated use of the product may be required to ensure that the surface remains wet [for contact time(s) listed on the label.] [OR for five (5) minute[s].] Let air dry.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean and decontaminate critical or semi-critical medical devices prior to sterilization or [high level disinfection] [or HLD].

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. *[Statement not required for residential or household use products.]*

*[Use storage and disposal Statement A if canister, bucket, pail or refill dispenser directions used. Use storage/disposal Statement B if Solo Pak, Portable Pack, Soft Pack, Flow Pack, Eco-Pak, Packet, Pouch, or [refill packet/package] directions used.]*

**Storage:** Store this product in a cool, dry area, away from direct sunlight.

*[Statement A:]*

**Storage:** Do not store near heat or open flame. When not in use, keep [center cap of] lid closed to prevent moisture loss.

**Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

**Canister [or Container or Bucket or Pail or Dispenser] Disposal:** Nonrefillable canister [or container or bucket or pail or dispenser]. Do not reuse or refill this canister [or container or bucket or pail or dispenser]. Offer for recycling. If recycling is not available, put in trash collection.

*[If refillable dispenser is being used, substitute the following: Refill Package [or Canister or Container or Bucket or Pail or Dispenser] Disposal:* Offer for recycling. If recycling is not available, discard in trash.]

*[Statement B:]*

**Storage:** Do not store near heat or open flame. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet. **Packet [or Package or Pouch or Container or Dispenser] Disposal:** Put empty Solo® Pak [or Portable Pack or Soft Pack or Flow Pack or Ecopak or [refill] packet or packaging or pouch]] in trash collection.

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March 15, 2019



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T Number: 1 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:53:22 AM -04'00'

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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

I Number: 2 Author: jmcfarle Subject: Highlight Date: 9/9/2019 11:58:12 AM -04'00'

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remove brackets and change to visibly wet.

T Number: 3 Author: jmcfarle Subject: Highlight Date: 9/9/2019 11:57:39 AM -04'00'

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remove brackets. There is only one organism with a contact of 5 minutes. No need for a qualifier.

[Optional Use Sites]

[Table 1: Hard, nonporous use sites/surfaces]

[Areas of Use:] [Hospital and Healthcare Settings:] [2]ay be used on hard, nonporous surfaces in[:] [Optional Use Sites]			
Ambulances	Ambulatory Surgical Centers (ASC)	[3]nesthesia	Ambulance equipment surfaces
Bed railings	Bladder scan	Blood glucose meters	Blood pressure cuffs
CAT Labs	CCU	Critical Care Units (CCU)	Central Supply
Cabinets	Cardiac gym equipment	Cardiac monitors	Carts
Clinics	Chairs	Counters	Dental Offices
Dental chairs	Dental unit instrument trays	Dental countertops	Defibrillators
Doctors' Offices	Dopplers	Donation Centers ([blood][plasma][semen][milk ][apheresis])	Dialysis Clinics
E.R.	Emergency Rooms	Emergency Medical Settings	Emergency Vehicles
Endodontic equipment such as apex locators	Exam tables	Electronic thermometers	Eye Surgical Centers
Gurneys	Healthcare Settings	Health Care Facilities	Home Health Care
Hospitals	Hospices	Intensive Care Units (ICU)	Isolation Areas
Isolettes	IV poles	IV pumps	ICU
[Interior and exterior surfaces of] infant incubators	[Interior and exterior surfaces of] infant warmers	[4]aboratory	Laundry rooms
Long Term Care Centers	Laboratory equipment and surfaces	Loupes	Medical Intensive Care Units (MICU)
Newborn nursery	Nursing homes	Nursing rooms	Neonatal Intensive Care Units (NICU)
Operating Rooms (OR)	Oncology Facilities	Ophthalmic Offices	Orthopedics
Out-Patient Surgical Centers (OPSC)	Operatory light switches	Ophthalmoscopes	Otoscopes
Operating room tables and lights	Oxygen hoods	Patient lift equipment	Physical Therapy (PT) equipment surfaces
Patient Care Areas	Patient Rooms	Pediatrics	Pediatric Intensive Care Units (PICU)
Physical therapy	Physicians' offices	Pulse oximeter	Post-Operative Care Unit (PACU)
[5]adiology	Radiology equipment	[6]espiratory therapy	Recovery Rooms
[7]ehabilitation	Rest rooms	Skilled Nursing Facility	Surgery Intensive Care Unit (SICU)
Surgical Centers	[8]urgery	Slit lamps	Spine back boards
Stretchers	Stools	Tables	Telemetry equipment
Stethoscopes	Telephones	Toilet seats	Transport vehicles
Tympanic thermometers	Urgent Care Centers	Workstations on wheels (WOW)	X-Ray

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March 15, 2019

<b>T</b>	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 3:50:21 PM -04'00'
	Please apply changes to highlighted words below to ensure that all use sites/surfaces in the table are use sites or surfaces. For example, "Surgery" is neither a use site or surface. Revise to "surfaces in surgical center" or "Surgery Center". Similarly, revise "radiology", "physical therapy", "respiratory therapy", "anesthesia", "X-ray", "Orthopedics".			
<b>T</b>	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 3:48:58 PM -04'00'
	this cannot be in brackets.			
<b>T</b>	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/6/2019 3:48:28 PM -04'00'
<b>T</b>	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:37:37 AM -04'00'
<b>T</b>	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:37:22 AM -04'00'
<b>T</b>	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:38:10 AM -04'00'
<b>T</b>	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:37:26 AM -04'00'
<b>T</b>	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:37:16 AM -04'00'

<b>Hard, nonporous outside surfaces of: amalgamators and dental curing lights</b>	<b>Hard, nonporous outside surfaces of: anesthesia machines and respiratory therapy equipment</b>	<b>Hard, nonporous outside surfaces of: apheresis machines</b>	<b>Hard, nonporous outside surfaces of: diagnostic equipment</b>
<b>Hard, nonporous outside surfaces of: dialysis machines</b>	<b>Hard, nonporous outside surfaces of: patient monitoring equipment</b>	<b>Hard, nonporous outside surfaces of: patient support and delivery equipment</b>	<b>Hard, nonporous outside surfaces of: pulp testers and motors</b>
<b>Hard, nonporous outside surfaces of: toilets</b>	<b>Hard, nonporous outside surfaces of: ultrasound monitors</b>	<b>Hard, nonporous outside surfaces of: ultrasound transducers and probes.</b>	

**[Table 2: Surface Materials]**

<b>Surface Materials:</b>		
ABS plastic	Aluminum	Brass
Copper	Corian® <sup>2</sup>	Chrome
Formica® <sup>1</sup>	Glass	Glazed ceramic
Laminate Surfaces	Linoleum	Polycarbonate
Polyester	PVC	Plexiglas® <sup>3</sup>
Porcelain	Polybutylene Terephthalate (PBT)	Rubber
Stainless Steel	Treated Wood surfaces	Titanium
Vinyl	Zinc	

<sup>1</sup> Formica [®] is a [registered] trademark of The Diller Corporation

<sup>2</sup> Corian [®] is a [registered] trademark of E. I. du Pont de Nemours and Company

<sup>3</sup> Plexiglas [®] is a [registered] trademark of Arkema, Inc.

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March 15, 2019

## Page: 9

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T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:00:48 PM -04'00'
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Must remove, comes into contact with human mucous membrane and is classified as semi-critical.

T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:01:50 PM -04'00'
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Qualify as hard, nonporous

[Symbols including asterisks, bullets or footnotes and similar may be used to designate categories of organisms.]  
[ATCC numbers are not required to be listed on production label. Organisms may be listed in a table and in any order.]

**[Table 3: List of Disinfection Organisms]**  
**Disinfection**

Contact Time	Microorganism	Identification Number	Antibiotic Resistance demonstrated
<b>1 Minute</b>	<b>Bacteria</b>		
	Carbapenem Resistant - <i>Klebsiella pneumoniae</i>	[ATCC BAA-1705]	[(CRKP)]
	<i>Acinetobacter baumannii</i> – Multidrug Resistant (MDR)	[ATCC 19606]	[Effective against organism resistant to Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime, Ceftriaxone]
	Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	[ATCC 33592]	
	Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	[ATCC 51575]	
	NDM-1- Positive <i>Enterobacter cloacae</i>	[CDC 1000654]	
	ESBL Positive <i>Escherichia coli</i>	[ATCC BAA-196]	
	<b>Bacteria</b>		
	<i>Salmonella enterica</i>	[ATCC 10708]	
	<i>Pseudomonas aeruginosa</i>	[ATCC 15442]	
	<i>Staphylococcus aureus</i>	[ATCC 6538]	
	<b>Bloodborne Pathogens</b>		
	*Hepatitis B virus (HBV) - Duck HBV†		
	*Hepatitis C virus (Human) (HCV) – Bovine Diarrhea Virus† [Strain NADL, American BioResearch Lab]		
	*HIV-1† (AIDS virus) [Strain HTLV-IIIa]		
	<b>Non-Enveloped Viruses*</b>		
	*Adenovirus type 5 [Strain Adenoid 75]	[ATCC VR-5]	
	*Rhinovirus type 1A [Strain 2060]	[ATCC VR-1559]	
	*Rotavirus [Strain WA]	[ATCC VR-2018]	
	*Norovirus (Feline Calicivirus) [Strain F-9]	[ATCC VR-782]	
	<b>Enveloped Viruses*</b>		
	*Herpes Simplex virus type 2 [Strain G]	[ATCC VR-734]	
	*Influenza A virus (H3N2) / Strain A/Hong Kong 8/68	[ATCC VR-544]	
	*Respiratory Syncytial virus (RSV), [Strain Long]	[ATCC VR-26]	

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All directions may be written in numbered form or in paragraph form

March 15, 2019



	<b>Pathogenic Fungi</b>		
	<i>Candida albicans</i>	[ATCC 10231]	
	<i>Trichophyton interdigitale</i> [(Formerly known as) [(Tested as) <i>Trichophyton mentagrophytes</i> ]]	[ATCC 9533]	
	<b>Mycobacterium (TB) [Tuberculocidal]</b>		
	<i>Mycobacterium bovis</i> BCG (Tuberculosis) (TB)		
<b>5 min[utes]</b>	<b>C.difficile [Spores]</b>		
	<i>Clostridium difficile</i> [spores]	[ATCC 43598]	

[Effective against all listed organisms in the presence of organic soil (5% blood serum)]  
[Optional organism listings and claims:]

[Note: The following Emerging Viral Pathogen claims will not appear on product labels]

### **Emerging Viral Pathogen Claims**

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<u>1)ne of the following:</u> Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	<u>2)ne of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	<u>3)wo of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

#### **THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included.  
A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.  
When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim.  
+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"  
Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.  
Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR  
The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.  
The word "and" and symbol "&" can be used interchangeably  
All directions may be written in numbered form or in paragraph form  
March 15, 2019

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T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:13:16 PM -04'00'
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Please Remove

T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:13:22 PM -04'00'
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Please Remove

T	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:13:30 PM -04'00'
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Please Remove



[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or nonporous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [pathogen specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

**Optional Claims and Descriptors** (Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used)

<b>1) Disinfecting Claims</b>	
An effective method to deodorize and disinfect against odor-causing organisms on hard, nonporous surfaces [listed on this label]	An effective way to disinfect hard, nonporous [environmental] surfaces listed on this label.
An effective [Great][Appropriate][ideal][approach] [method] [process] [solution] [product][way] to [clean] [2]protect [3]guard [disinfect] [4]eradicate [kill] [destroy] [5]eliminate [against] [odor-causing] [7]nosocomial[8]hospital borne[6]hospital acquired [bacteria] [germs] [norovirus] [viruses*] [cold & flu viruses*] [pathogens][9]ESCAPE bacteria [harmful] [fungus] [organisms][microorganisms] on hard, non-porous surfaces[fomite]	Antibacterial
[Antibacterial] [Antimicrobial] health club equipment wipe	Antimicrobial
Bacteria [and] [or virus*] [and] [or germ] fighting [formula]	Bactericidal
[Bactericidal], [Tuberculocidal], [Fungicidal], [and] [Virucidal*] [in] [1 [one] minute] [or 60 seconds]	[Bactericidal], [Tuberculocidal], [Fungicidal], [Virucidal*][and] [10]poricidal <sup>(A)</sup> [(^C.difficile [spores])]
Bathroom disinfectant	Broad Spectrum Disinfectant
Broad spectrum efficacy	Broad spectrum [microorganism coverage]
Can help reduce the [13]risk of cross contamination on treated surfaces	[11]completely inactivates [viruses*] [insert virus(es)*]
[14]daily defense against germs [or pathogens]	Demonstrates 99.9[15] reduction of [bacteria] [insert bacteria]
Designed for killing [Clostridium difficile] [or C. difficile] [or C.diff] [spores] on hard, nonporous surfaces [in hospitals] [or Insert area of use facility from pages 6 - 7]	Demonstrates [6] [six] [16]9999% [log] reduction against [Clostridium difficile] [or C. difficile] [or C.diff] [spores] [in 5 [or five] minutes]
Deodorizes [,] [cleans,] and kills [17]common household germs* [use at least two bacteria and two viruses from the organism list]	[Destroys] [Deactivates] [[Helps] Eliminate[s]] [Clostridium difficile [spores]] [or C.difficile [spores]] [or C.diff [spores]] on hard, nonporous surfaces [in hospitals] [[or Insert area of use facility or from pages 6 - 7]
Disinfect external hard, nonporous surfaces of ultrasound transducers and probes	Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]
Disinfects precleaned hard, nonporous surfaces	[Disinfects] hard, nonporous surfaces

**THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.

When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim

+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel "Kills germs" Back panel "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

<b>T</b>	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:31:35 PM -04'00'
	Please remove the following highlighted claims as they are false and/or misleading. Please refer to chapter 12 of the label review manual for the agency. In addition please remove all cleaning claims from this section.			
<b>T</b>	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:41:38 AM -04'00'
	Must remove.			
<b>T</b>	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:43:02 AM -04'00'
	Must remove			
<b>T</b>	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:41:18 AM -04'00'
	Must remove.			
<b>T</b>	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:43:25 AM -04'00'
	Must remove.			
<b>T</b>	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:49:26 AM -04'00'
	Must remove.			
<b>T</b>	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:48:19 AM -04'00'
	Must remove.			
<b>T</b>	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:48:54 AM -04'00'
	Must remove.			
<b>T</b>	Number: 9	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:39:25 AM -04'00'
	Please remove, not all ESKAPE pathogens have been tested for this product. Testing was conducted against <i>Enterococcus faecalis</i> and not <i>Enterococcus faecium</i> .			
<b>T</b>	Number: 10	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:51:26 AM -04'00'
	Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.			
<b>T</b>	Number: 11	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:57:04 AM -04'00'
	Remove "completely inactivates [viruses]". The log reduction achieved may be claimed (e.g. 99.9%) however claims for complete inactivation are not acceptable.			
<b>T</b>	Number: 12	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:50:17 AM -04'00'
	Must remove.			
<b>T</b>	Number: 13	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:49:59 AM -04'00'
<b>T</b>	Number: 14	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:50:43 AM -04'00'
	Remove "daily defense against germs [or pathogens]" as it implies protection from disease.			
<b>T</b>	Number: 15	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:07:04 AM -04'00'
	change to 99.9%.			
<b>T</b>	Number: 16	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:07:13 AM -04'00'
	See above.			
<b>T</b>	Number: 17	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:40:29 AM -04'00'

Comments from page 12 continued on next page

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or nonporous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [pathogen specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/nonporous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

**Optional Claims and Descriptors** [Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used]

<b>Disinfecting Claims</b>	
An effective method to deodorize and disinfect against odor-causing organisms on hard, nonporous surfaces [listed on this label]	An effective way to disinfect hard, nonporous [environmental] surfaces listed on this label.
An effective [Great][Appropriate][ideal][approach] [method] [process] [solution] [product][way] to [clean] [protect] [guard] [disinfect] [eradicate] [kill] [destroy] [eliminate] [against] [odor-causing] [nosocomial][Hospital borne][hospital acquired] [bacteria] [germs] [norovirus] [viruses*] [cold & flu viruses*] [pathogens] [ESKAPE bacteria] [harmful] [fungus] [organisms][microorganisms] on hard, non-porous surfaces[fomite]	Antibacterial
[Antibacterial] [Antimicrobial] health club equipment wipe	Antimicrobial
Bacteria [and] [or virus*] [and] [or germ] fighting [formula]	Bactericidal
[Bactericidal], [Tuberculocidal], [Fungicidal], [and] [Virucidal*] [in] [1 [one] minute] [or 60 seconds]	[Bactericidal], [Tuberculocidal], [Fungicidal], [Virucidal*][and] [Sporicidal <sup>(A)</sup> ] [(^C.difficile [spores])]
Bathroom disinfectant	Broad Spectrum Disinfectant
Broad spectrum efficacy	Broad spectrum [microorganism coverage]
Can help reduce the risk of cross contamination on treated surfaces	Completely inactivates [viruses*] [insert virus(es)*]
Daily defense against germs [or pathogens]	Demonstrates 99.99% reduction of [bacteria] [insert bacteria]
Designed for killing [ <i>Clostridium difficile</i> ] [or C. difficile] [or C.diff] [spores] on hard, nonporous surfaces [in hospitals] [or Insert area of use facility from pages 6 - 7]	Demonstrates [6] [six] [99.9999%] [log] reduction against [ <i>Clostridium difficile</i> ] [or C. difficile] [or C.diff] [spores] [in 5 [or five] minutes]
Deodorizes [,] [cleans,] and kills common household germs* [use at least two bacteria and two viruses from the organism list]	[Destroys] [Deactivates] [[Helps][18]minute[s]] [ <i>Clostridium difficile</i> [spores]] [or C.difficile [spores]] [or C.diff [spores]] on hard, nonporous surfaces [in hospitals] [[or Insert area of use facility or from pages 6 - 7]
Disinfect external hard, nonporous surfaces of ultrasound transducers and probes	Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]
Disinfects precleaned hard, nonporous surfaces	[Disinfects] hard, nonporous surfaces

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+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills

Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

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The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

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Must remove. This is misleading to the user.

Number: 18      Author: jmcfarle      Subject: Highlight      Date: 9/9/2019 7:43:53 AM -04'00'

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must Remove.



Disinfectant wipe	Disinfects on the go
Disinfects [.] [cleans] [and deodorizes] hard, nonporous surface(s) [that people touch] [in] [just] [1 minute] [or 60 seconds]	Disinfects [health club equipment] [treadmill handles] [elliptical handles] [exercise bike handles] [weight benches]
Effective against [ <i>Clostridium difficile</i> ] [or <i>C.difficile</i> ] [or <i>C.diff</i> ] [spores] [in 5 [or five] minutes]	Effective against bacteria and viruses* [use at least two bacteria and two viruses from the organism list]
Effective in the presence of 5% blood serum contamination	Effective against [.] [the following micro-organisms] [list organisms] on hard, nonporous surfaces
Effective against a broad range of microorganisms	Everyday [disinfection] [1] [protection] against [list microorganism]
[2] [Fast] [Convenient] [Portable] way to disinfect hard, nonporous surfaces	Fungicidal
[Five] [5] minute [3] [poricidal] [^(^ [ <i>Clostridium difficile</i> ] [or <i>C.difficile</i> ] [spores])]	Germicidal* [Wipe] [use at least two bacteria and two viruses from the organism list]
Hard, nonporous surface disinfectant	[Helps] [kill(s)] [4] [eliminate(s)] odor-causing bacteria
Just [or simply] wipe exterior toilet surface [or bathroom] germs* away	[Kills] [Disinfects] Norovirus [Feline Calicivirus] in 1 [one] minute
[Kills] [Effective against] [the following micro-organisms on hard, nonporous surfaces] [list organisms] [in] [just] [one] [1] [minute] [60 seconds]	Kills bacteria and viruses* [in the bathroom] [on the exterior toilet surfaces] [use at least two bacteria and two viruses from the organism list:]
Kills a wide range of pathogens	Kills bacteria in 1 minute
[Kills] [Effective against] 99[5] 999% of [ <i>Clostridium difficile</i> ] [or <i>C. difficile</i> ] [or <i>C.diff</i> ] [spores] [in 5 [or five] minutes]	Kills [ <i>Clostridium difficile</i> ] [or <i>C. difficile</i> ] [or <i>C.diff</i> ] [spores] [in 5 [or five] minutes]
[Kills] [Effective against] CRKP [(Carbapenem Resistant <i>Klebsiella pneumoniae</i> )] in 1[or one] minute	[Kills] [Effective against] MRSA [(Methicillin Resistant <i>Staphylococcus aureus</i> )] in 1 (one) minute
Kills Pandemic 2009 H1N1 influenza A virus	Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
[Kills] [Effective against] the [spore form of] <i>Clostridium difficile</i> [or <i>C. difficile</i> ]	[Kills] [Effective against] TB in [1] [one] minute
Kills odor causing bacteria	[Kills] [Effective against] viruses* in [only] [1] [one] minute
Leaves [bathroom] [office] [and other sites listed on this label] disinfected [and smelling fresh]	Multi-purpose disinfectant
[7] [Non-Bleach] [6] [poricidal] [^(^ [ <i>Clostridium difficile</i> ] [or <i>C. difficile</i> ] [spores])]] [8] [alcohol free] [quat free] [hospital] [disinfectant] [this is included as useful info for users needing a] [9] [bleach-free,] [alcohol free,] [quat free,] product	One [1] minute [or 60 seconds] [contact time] [***] [***5 minutes for <i>C.difficile</i> ]
One [1] minute [or 60 seconds] [kill] [contact] time reduces time to turnover room	One [1] minute [or 60 seconds] [general] disinfectant [***] [***5 minutes for <i>C.difficile</i> ]
One [1] minute [or 60 seconds] [Bactericidal] [.] [Virucidal*] [.] [Fungicidal] [.] [and] [Tuberculocidal]	One [1] minute [or 60 seconds] [kill] [contact] time on [X] microorganisms
One step [cleaner] [disinfectant] ** (***A precleaning step is required to kill <i>C.difficile</i> [spores] and <i>Mycobacterium bovis</i> (BCG)) [(Tuberculosis)] [(TB)]	One-Step [10] [cleaner/Disinfectant] [Grease and soap scum claims are not to be used on labeling with one-step] [11] [cleaning/disinfection claims. One step d] [12] [cleaner/disinfectant claim should not be used for <i>C.difficile</i> .]
Overall [13] [five] minute contact time	Perfect for disinfecting [exterior toilet surfaces] [around the exterior toilet surface]

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+All pesticidal "germ" claims must be linked to bacteria (minimum: *Salmonella* and *Staph*) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills *Salmonella enterica*, *Staphylococcus aureus*, Herpes Simplex Type 2, and Influenza A/Hong Kong"

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All directions may be written in numbered form or in paragraph form

March 15, 2019

T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:42:09 AM -04'00'
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Must Remove.

T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:02:56 AM -04'00'
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Must remove.  
this claim is reserved for products with contact times of 30 seconds or less.

T	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:51:46 AM -04'00'
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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

T	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:44:18 AM -04'00'
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Must remove.

T	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:19:47 PM -04'00'
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Change to 99.9%

T	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:52:08 AM -04'00'
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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

T	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:21:15 PM -04'00'
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this is misleading, please remove.

T	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:22:37 PM -04'00'
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See above.

T	Number: 9	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:23:18 PM -04'00'
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Please remove. This is misleading.

T	Number: 10	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:23:55 PM -04'00'
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please remove. One step is for disinfection.

T	Number: 11	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:24:14 PM -04'00'
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see above.

T	Number: 12	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:24:26 PM -04'00'
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see above.

T	Number: 13	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:25:02 PM -04'00'
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Must remove brackets. Cannot be 1 minute.

*[Product name] is virucidal against Adenovirus type 5, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Herpes Simplex Virus type 2 (causative agent of genital herpes), HIV-1, Influenza A virus (H3N2)/Hong Kong strain (representative of the common flu virus), Respiratory Syncytial Virus [RSV], Rhinovirus type 1a, Rotavirus (Strain WA), and Norovirus (Feline calicivirus) in the presence of organic soil (5% blood serum).	1]espiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
Reduces exposure to microorganism(s) from treated surface	2]educes risk of infections
Sani-HyPerCide [™] [®] [Wipe] [Disinfectants]	3]poricidal[ <sup>(A)</sup> ] ([^ [Clostridium difficile] [ or C. difficile] [spores]])
Surface disinfectant	Tuberculocidal
The 1-minute [germicidal*] [disinfectant wipe][*][5 minutes for C.diff]	The 5-minute [germicidal*] [disinfectant wipe]
Thick, heavy duty wipes are Bactericidal, Tuberculocidal and Virucidal* in 1 minute	Thick, large wipe disinfects
This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.	4]his product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
This product 5]eans, disinfects, and deodorizes hard, nonporous medical surfaces without any rinsing required[7]. [A thorough rinse with potable water is required for food contact surface.]	6]his product] controls the spread of germs on [most] hard, nonporous surfaces
This product disinfects [and cleans major soils]	7]his product meets EPA efficacy testing requirements [or standards] for hospital disinfection
Tough on germs, easy to use around patient[s] [areas]	Tough on germs, easy on surfaces
[The] easy [and] [or convenient] way to disinfect	8]he [complete] [and] [or total] [and] [or all facility] answer to [all] your disinfecting needs
Tough on germs, [excellent] [or ideal] [or great] for everyday use	Use [or cleans] [and] [or disinfects] on hard, nonporous healthcare surfaces
Use in places when you are concerned about bacteria [and] [or viruses*] [and] [or germs]	Use in public [or common places] where [bacteria [and] [or viruses*] [and] [or germs] may be of concern
9]se to preclean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection	[Use to] disinfect(s) hard, nonporous environmental surfaces listed on this label
Use where control of the hazards of cross contamination between treated surfaces is of prime importance	Versatile 10]eaner] disinfectant
Virucidal*	[Wipes out] [Kills] 11]minates] [List organisms] in [just] [1 minute] [or 5 minutes]
[Wipes out] [Kills] [the] flu virus* (*Influenza A/Hong Kong)	[Wipes out] [Kills] viruses* and bacteria [including the flu virus* (*Influenza A/Hong Kong)]
Wipes are [Bactericidal], [Tuberculocidal,] [Fungicidal,] [Virucidal*] in 1 minute [or 60 seconds]	

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The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:49:16 AM -04'00'
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Remove.

T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:14:56 AM -04'00'
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Must remove.

T	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:52:17 AM -04'00'
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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

T	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:50:31 AM -04'00'
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Remove.

T	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:31:01 PM -04'00'
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remove, not for this section.

T	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:15:36 AM -04'00'
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Revise the claim "This product controls the spread of germs on most hard, nonporous surfaces" to "This product reduces the spread of germs on most treated hard, nonporous surfaces"

T	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:28:04 PM -04'00'
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Must remove. This is misleading.

T	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:28:58 PM -04'00'
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Please remove. This is misleading.

T	Number: 9	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:32:03 PM -04'00'
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Must remove form this section.

T	Number: 10	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:30:40 PM -04'00'
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remove, this is disinfecting claims.

T	Number: 11	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:44:34 AM -04'00'
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Must remove.



### General Cleaning and Deodorizing Claims

[1]ppropriate [or Perfect or Great or Ideal] for Terminal Cleaning	Cleans [,] [Deodorizes,] and kills common household germs* [use at least two bacteria and two viruses from the organism list]
Cleans with [minimal][virtually no] residue	Cleans [tough stains]
Cleans [as it disinfects] [and disinfects]	Cleans and disinfects without alcohol
Deodorize hard, nonporous surfaces [Use to]	[2]eliminates [lingering] [food] odors on surfaces
[3]eliminates odors	[Gets rid of] [4]eliminates odors
Makes cleaning easier	Odor [eliminator] [neutralizer]
Powers through tough messes	Removes [odors] [dirt]
[Use to] Deodorize hard, nonporous surfaces	

### Formula Related Claims

A hydrogen peroxide solution impregnated in a wiping cloth	Are pre-measured to [have][contains][deliver] the recommended amount of germicidal solution, wipe after wipe
[5]leach-free [formula] [this is included as useful info for users needing a bleach-free product]	Contains no VOC-emitting ingredients
Compatible [for use on hard, nonporous surfaces commonly found in healthcare settings [listed on this label]]	Compatible with commonly used materials [in healthcare settings]
Compatible [with equipment surfaces]	Compatibility tested
[6]oes not contain bleach [this is included as useful info for users needing a bleach-free product]	No diluting or mixing required
[7]on-Bleach [this is included as useful info for users needing a bleach-free product]	Non-corrosive
Proprietary Formulation [product]	Ready to Use [disinfectant] [wipe]

### Formula Related Claims

[8]lcohol free [formulation][wipe][RTU][formula]	[9]leach [10]oricidal [formulation][wipe][RTU][formula]
[11]es not contain [bleach,] [alcohol,] [quat] [this is included as useful info for users needing a [bleach-free,][alcohol free,] [quat free] product]	Does not leave [visible] [residue][haze]
Dual action	Hydrogen peroxide [12]oricidal [formulation] [wipe] [RTU][formula]
Leaves virtually no [visible] [residue][haze]	[Low] [minimal] residue [formula]
Low streak formula	No mixing, measuring, [or rinsing] required
[14]n-abrasive formula	[13]n-Bleach,] [Non-alcohol,] [non-quat,] [this is included as useful info for users needing a [bleach-free,] [alcohol free,] [quat free] product]
Prevents [mixing][measuring][dilution] errors	[Product name] [is] a Hydrogen peroxide pre-saturated wipe

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March 15, 2019

T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 8:16:29 AM -04'00'
Must remove.				

T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:44:46 AM -04'00'
Must remove.				

T	Number: 3	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:45:02 AM -04'00'
Must remove.				

T	Number: 4	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:45:20 AM -04'00'
Must remove.				

T	Number: 5	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:35:56 PM -04'00'
Please remove, this is misleading.				

T	Number: 6	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:37:53 PM -04'00'
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T	Number: 7	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:37:58 PM -04'00'
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T	Number: 8	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:38:23 PM -04'00'
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T	Number: 9	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:53:03 AM -04'00'
Must remove, this is a hydrogen peroxide label.				

T	Number: 10	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:52:33 AM -04'00'
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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

T	Number: 11	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:38:14 PM -04'00'
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T	Number: 12	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 7:52:47 AM -04'00'
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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

T	Number: 13	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:39:23 PM -04'00'
Please remove.				

T	Number: 14	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:38:59 PM -04'00'
Must remove.				

[Product name] is pre-measured to [have][contains][deliver] the recommended amount of [germicidal] [bactericidal] [virucidal*][fungicidal][Tuberculocidal][ <u>1</u> poricidal] [solution][formula] wipe after wipe	Requires no mixing or measuring and are ready-to-use
Ready to Use [disinfectant] [wipe]	Shelf-Stable formula
Unique Formula	Will not corrode surfaces
<u>2</u> With a bleach-free formula <i>[this is included as useful info for users needing a bleach-free product]</i>	

### **Packaging Related Claims**

[Convenient and] easy to use	Contains [number] canisters [plus] [and] [number] [refills]
Convenient [Size]	Close lid [after use][when not in use]
Designed for [EVS][ES][Environmental Services][housekeeping][services] [extra-large wipe in bucket and refill]	Designed for easy dispensing [and][or] [ease of use]
Dispenses [or Comes out] one wipe at a time	Dispenses one wipe at a time
Dispensing is effortless[!]	Easy [and] [or Better] [Dispensing] Lid [or Closure] [or Cap]
Easy to carry	Easy [to use] [to refill]
[Easy] [Convenient] [Portable] way to disinfect hard, nonporous surfaces	Easy [and convenient] way to [touch-up] [bathroom] [office] [and other sites listed on this label] everyday
Easy to Open [or Thread]	Easy to pull wipes
[Easy] pop-up tub	Easy start lid [package]
Easy to [store] [and] [or stack]	Easier Than Ever to Use [or Pull] [Wipes] [Out][!]
Easy to use design	Easy [to use] dispenser
Easy to Use Lid	Easy [to Use] Dispensing [or Dispenser][!]
Easy [and] [or Simple] [or Better] Dispensing[!]	Effortless dispensing[!]
Easy to use [package] [canister] [container] keeps [your] wipes moist	[Economical] Refill[s] [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] -pack
[Economical] Refills [now] available	Includes _ count refill [pack] [contains] _ wipes
Moisture-lock lid	Multiple sizes available to meet disinfecting needs
Multi-pack	[Multi [-refill] pack]
No canister needed	Next wipe pops up automatically [every time] [!]
No threading [required]	One [wipe] at a time dispensing
[Please] keep lid closed	[Package] <i>[insert type of package]</i> made from [x%] recycled materials
Pop-up [dispensing] [top]	Recyclable [package]
[Refill] package contains <i>[various numbers]</i> [refill(s)]	Refill [size] [pack] [value pack]
Twin pack	Trial [pack]
X% reduction in packaging [material]	X% [more] [wipes] [free] [vs. Z count] [canisters] [packs]

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March 15, 2019

---

T Number: 1 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:54:14 AM -04'00'

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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

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T Number: 2 Author: jmcfarle Subject: Highlight Date: 9/9/2019 12:39:59 PM -04'00'

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Please remove.



### **Towelettes Related Claims**

[Absorbent] wipe	[Cloth-like texture][Textured] [strong] [for] [with] [cleaning] [and][or] [disinfecting] power
Durable, low-lint designed for sensitive equipment surfaces	Embossed wipe is low linting [ for sensitive equipment surfaces]
[Extra] large [disinfecting] [Y" x Z" compared to our A" x B" size] wipe[s]	[Heavy] cloth-like towel
Larger wipe covers [more surface area] larger area [with less effort][!]	Larger, thicker wipe [with embossed design] (may be used for 6 months on marketed label)
Large[r] [wipe][s]	Low linting [Low tearing]
	New larger, thicker wipe [with embossed design] (may be used for 6 months on marketed label)
No [pinched fingers] [rips] [tears]	New thicker wipe with embossed design (may be used for 6 months on marketed label)
Non-scratching [wipe]	Nonwoven disposable cloth
Picks up [particles] [dust] [dirt] [hair] [crumbs]	Strong, durable embossed textured wipe deodorizes
Strong, durable low-lint wipe [designed for sensitive equipment surfaces]	[Strong,] wipe helps remove [dried] blood [and] [bodily fluids] from surfaces
[Strong,] wipe helps remove dirt and grime from surfaces	Textured embossed design [deodorizes hard, non-porous surfaces]
Tear at perforation	Tear resistant
Test wipe on small inconspicuous area first	Thick[,][absorbent][Extra [Large][or Small] wipe
Thick, textured wipe with embossed design	Thick [strong] wipe [material]
Wet wipes	[Wiping] [soft] side for disinfecting
X# [pre-saturated] towelettes [X" x Y"]	X% bigger [quilted] [wipes] [vs. X" x Y" wipes]
X" x Y" [wipes]	

### **Other Product Related Claims**

After use, just toss wipe(s) away	A [Sani-Surface®] [Sani-Cloth®] Brand
Always ready to use	A nonwoven disposable cloth for use [in hospitals] [other critical care areas] [or insert area of use facility] where control between treated surfaces is required.
Brought to you by [the makers of] [product name] [Sani-Cloth®] [PDI] [Sani Professional] [products] [brand]	Can help reduce the risk of cross contamination on treated hard, nonporous surfaces
Compatible with a wide variety of surfaces	Convenient
Delivers [consistent][specific] [amount of solution] concentration every time[!]	[Designed] [for] [with] [the] Environmental Services [EVS][ES][Housekeeping][Services] Professional[s] [in] [mind][!]
[Designed] For daily use [or Use for daily] [or] [discharge] cleaning [in Healthcare facilities]	[Designed] For [isolation][or terminal] cleaning [in healthcare facilities]
Designed for healthcare	Does not require [the hassle of] dispensing systems
Does not require PPE under normal condition[2] [Per facility protocol]	Do not use on natural marble, windows, unpainted wood, clear plastic, or colored grout.
Effective [every day] [multisurface] [all facilities] [cleaner][disinfectant]	Effective cleaning on dried blood

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March 15, 2019

T	Number: 1	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:43:24 PM -04'00'
	Please remove.			
T	Number: 2	Author: jmcfarle	Subject: Highlight	Date: 9/9/2019 12:42:36 PM -04'00'
	Please remove.			

[Excellent] [Broad] surface compatibility	[EVS][ES] [Environmental Services] [Housekeeping][Services] use
Eliminates daily mixing and measuring	Environmental services use
Expiration date [or EXP] [insert date]	Exclusive to PDI, Inc.
For direct application	For [hospital] [healthcare] use
[For] daily use	[For] nonfood contact surfaces [only]
From the makers of Sani-Cloth® [Brand][products]	1]elps prevent cross contamination on hard, nonporous treated surfaces
Hospital [or insert area of use facility from page 6 - 7] [disinfectant] [disinfection] [disinfectant-cleaner]	[Ideal] for use on high-touch, hard, nonporous surfaces
Ideal product form for use around patients and staff	© [insert year] [insert company name]
Just [pull] wipe and toss	Large[r] Surface[s]
Made [or manufactured] in [USA] [Of Domestic and [Foreign] [Imported] Materials] [Made in [insert country]]	Meets OSHA Bloodborne Pathogen Standard [or AHE Practice Guidance for environmental cleaning] [CDC Guidelines for disinfection and sterilization in healthcare settings]
Not for sale in [insert name of state(s)]	No sponges, no rags, no buckets, no mess
Not available in private label	Not for sale [or use] after [insert date]
2]educe [risk of] cross contamination on hard, nonporous surfaces	Use by [insert date]
Use on hard, nonporous surfaces only: [stainless steel] [Formica®] [glass] [glass tables] [glazed tile] [Test solution on a small inconspicuous area first.] [Formica® is a registered trademark of The Diller Corporation.]	Value
Versatile	Where control of the hazards of cross contamination between treated surfaces is of prime importance
[Product name] is a germicidal wipe containing a Hydrogen peroxide based solution. Recommended for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard, nonporous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. [Formica® is a registered trademark of The Diller Corporation.]	

New (may be used for 6 months on marketed label)

**Note: The following claims can be used only for 6 months]**

[Better] [New] [Improved] [Stronger] [Thicker] Wipe [!]

[Better] [new] [&] [improved] [dispensing] lid [closure] [cap] [package] [dispensing] [better] [than before]

[Cleans] [better than ever]

New and improved

[New] [Package] [packaging] uses [x%] less material (plastic) [then] [when compared to] [regular] containers [or canisters]

New thicker and larger embossed wipe cleans more surface area

New r[4]n-bleach[3]poricidal<sup>(A)</sup> disinfectant [wipe] [(^ [C.difficile] [or C.difficile] [or C.diff] [spores])]

New Hydrogen Peroxide [H<sub>2</sub>O<sub>2</sub>] Formulation

New[3]poricidal<sup>(A)</sup> Hydrogen Peroxide [H<sub>2</sub>O<sub>2</sub>] Formulation [(^ [Clostridium difficile] [or C.difficile] [or C.diff] [spores])]

[Now] [Reinforced] [With] Quilted [strength]

Now with [%] more towel

Now with [#] more wipes

[Stronger] more durable [wipe]

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March 15, 2019

---

T Number: 1 Author: jmcfarle Subject: Highlight Date: 9/9/2019 8:17:59 AM -04'00'

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remove the claim "Helps prevent cross contamination on hard, nonporous treated surfaces." Claims for prevention are not acceptable.

---

T Number: 2 Author: jmcfarle Subject: Highlight Date: 9/9/2019 8:11:42 AM -04'00'

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change to cross contamination on treated hard nonporous surfaces".

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T Number: 3 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:54:27 AM -04'00'

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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

---

T Number: 4 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:54:48 AM -04'00'

---

Must remove, this is a hydrogen peroxide label. This is misleading.

---

T Number: 5 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:55:08 AM -04'00'

---

Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.



Thick(er) [wipe] [with] cloth-like texture  
X% [Bigger] [larger] [quilted] wipes  
[X%] thicker wipes

---

[Graphics depicting use sites listed on this label can appear on product label and labeling.]  
[The following graphics and statements are optional.  
They may be placed anywhere on label/container.]

The following is optional and may appear as verbiage or as a graphic:

- H<sub>2</sub>O<sub>2</sub> [Hydrogen Peroxide] formulation
- Effective against [C. difficile][C.diff][Clostridium difficile][spores]
- H<sub>2</sub>O<sub>2</sub> [Hydrogen Peroxide] formulation effective against [C. difficile][C.diff][Clostridium difficile][spores]
- 1poricidal formulation effective against [C. difficile][C.diff][Clostridium difficile][spores]
- 3Non-bleach 2poricidal<sup>[A]</sup> formula
- Bactericidal formulation effective against [insert microorganism]
- Virucidal\* formulation effective against [insert microorganism]
- Bactericidal, Virucidal\*, Fungicidal, Tuberculocidal [1 minute or 60 seconds]
- 4Non-alcohol formula
- Non-bleach 5poricidal<sup>[A]</sup> formula
- 6Non-quat formula
- Do not flush
- 7Non-bleach formula
- FOR USE ON HARD, NONPOROUS SURFACES ONLY
- Do not freeze
- Do not allow to freeze
- Not a Baby Wipe
- Not a Skin Wipe
- Not For Use On Skin

[(^[Clostridium difficile] or [C. difficile] [spores])]

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T Number: 1 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:55:25 AM -04'00'

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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

---

T Number: 2 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:55:38 AM -04'00'

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Revise "Sporicidal" to "Disinfectant with sporicidal activity" to be consistent with terminology in the 810.2100 guideline.

---

T Number: 3 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:55:54 AM -04'00'

---

Must remove, this is hydrogen peroxide label.

---

T Number: 4 Author: jmcfarle Subject: Highlight Date: 9/9/2019 12:44:43 PM -04'00'

---

Please remove.

---

T Number: 5 Author: jmcfarle Subject: Highlight Date: 9/9/2019 7:56:22 AM -04'00'

---

remove, see above.

---

T Number: 6 Author: jmcfarle Subject: Highlight Date: 9/9/2019 12:44:59 PM -04'00'

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Please remove.

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T Number: 7 Author: jmcfarle Subject: Highlight Date: 9/9/2019 12:45:10 PM -04'00'

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see above.



This graphic shows use of the wipe dispenser



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A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.

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+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



**THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired

When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim

+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs" Back panel: "Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A/Hong Kong"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

March 15, 2019

## McFarley, Jake

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Wednesday, September 25, 2019 4:05 PM  
**To:** McFarley, Jake  
**Cc:** Bain, Zeno  
**Subject:** RE: 9480-RA 30 Regulatory Determination Letter

Thank you Jake!

We will be waiting for the Stamped Label hopefully tomorrow. We appreciate your patience and hard work to get this done for us.

Have a great evening!

Jean Claude

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Wednesday, September 25, 2019 3:55 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA 30 Regulatory Determination Letter

Hello Jean Claude,

Thank you I confirm receipt. This will most likely get stamped tomorrow. I appreciate your patience.

I will message you tomorrow and follow up.

Thank you and have a good afternoon,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Wednesday, September 25, 2019 11:24 AM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA 30 Regulatory Determination Letter

Hi Jake,

Attached are the two master labels, one clean and one highlighted. I removed the phrase containing "eliminates", I also removed any references to "diff, Diffex and Diffx" in the alternate brand names. Please let me know if you need anything else, hopefully we will get the approval today.

Thank you!

Jean Claude

---

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Wednesday, September 25, 2019 10:35 AM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** 9480-RA 30 Regulatory Determination Letter

Good Morning Jean Claude,

I hope that you are doing well. Please see the attached 30 day letter. After discussion with the efficacy team about the 'sani' name and the fact that PDI's other products have this name we have agreed to allow it for this product. However, the 'Diff' must be removed from the alternate brand names. In addition please note that under the "general cleaning and deodorizing claims" the phrase 'eliminates' was included in the pre-decisional letter to be removed. Please remove this from the label.

I have annotated these in the attached letter and label. Please send over a revised label and we look forward to moving forward with this as quickly as possible.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

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## McFarley, Jake

---

**From:** McFarley, Jake  
**Sent:** Wednesday, September 25, 2019 3:30 PM  
**To:** Bain, Zeno  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC  
  
**Categories:** Completed

Oh yeah I talked to Sergey and he said that he would fix it tomorrow and attached the signed CSFs. Should we wait to do the PRIA until tomorrow?

Jake

---

**From:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Sent:** Wednesday, September 25, 2019 3:29 PM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Subject:** FW: CTT BEAN REG # (9480-RA) DP (452031) PC

Did you see this?

Thank you

Zeno

---

**From:** Hicks, Karen <Hicks.Karen@epa.gov>  
**Sent:** Wednesday, September 25, 2019 1:57 PM  
**To:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

That was logged out August 23. Sergey should have it. It may be in Documentum. I am ccing Sergey on this for the status.

Thank you!

---

**From:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Sent:** Tuesday, September 24, 2019 4:59 PM  
**To:** Hicks, Karen <Hicks.Karen@epa.gov>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

Sorry, one more thing, I had to close the bean to issue the 30-day letter (to close the PRIA), so I closed it as acceptable for the MRIDs and used the science deadline. We haven't sent anything to the registrant, so you can change it if you need to.

Thank you

Zeno



---

**From:** Bain, Zeno  
**Sent:** Tuesday, September 24, 2019 4:29 PM  
**To:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

I'm going to do a 30-day label review for this one to address some other items, which will give us a little time to get the PC review done in the meantime. Please let me know how it is going when you can. There shouldn't be any issues because this is a wipe, using a product that was previously registered.

Thank you

Zeno

---

**From:** Bain, Zeno  
**Sent:** Tuesday, September 24, 2019 1:45 PM  
**To:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>  
**Cc:** McFarley, Jake <[mcfarley.jake@epa.gov](mailto:mcfarley.jake@epa.gov)>; Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

Hi Karen

This PRIA is due today. We are having some issues with the registrant on other label language and they are asking for the review now. I apologize for the urgency - Jake should have followed up again with Sergey you last week and I should have followed up with you. Can you check into this and let me know the status? Also a heads up if there are issues would be helpful.

Thank you

Zeno

---

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Sent:** Friday, September 13, 2019 4:43 PM  
**To:** Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Cc:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>; Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

Hello Sergey,

Have you heard anything about this review? The PRIA is due on September 24<sup>th</sup>.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

---

**From:** Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Sent:** Monday, September 9, 2019 7:15 AM  
**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

Good morning, Jake,  
this PC package has been sent to contractor via Lorrie Montford.  
I already inquired about it. No answer insofar.

Regards,  
Sergey Alekseyev  
Chemist  
S-8831  
308 8167

---

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Sent:** 06 September, 2019 11:03 AM  
**To:** Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Cc:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

Good Morning Sergey,

I hope that you are doing well. Have you had the chance to complete this review?

Thank you,

Jake

---

**From:** Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Sent:** Wednesday, May 22, 2019 12:21 PM  
**To:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>  
**Cc:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Subject:** RE: CTT BEAN REG # (9480-RA) DP (452031) PC

People, TechScreen has been done. It's positive.

Regards,  
Sergey Alekseyev  
Chemist  
S-8831  
308 8167

---

**From:** Hicks, Karen  
**Sent:** 22 May, 2019 11:51 AM  
**To:** Alekseyev, Sergey <[Alekseyev.Sergey@epa.gov](mailto:Alekseyev.Sergey@epa.gov)>  
**Cc:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Subject:** FW: CTT BEAN REG # (9480-RA) DP (452031) PC

Already assigned to you Sergey

---

**From:** McFarley, Jake  
**Sent:** Tuesday, May 07, 2019 1:55 PM

**To:** Hicks, Karen <[Hicks.Karen@epa.gov](mailto:Hicks.Karen@epa.gov)>; Tao, Jenny <[Tao.Jenny@epa.gov](mailto:Tao.Jenny@epa.gov)>; OPP AD CTT DP  
<[OPP\\_AD\\_CTT\\_DP@epa.gov](mailto:OPP_AD_CTT_DP@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** CTT BEAN REG # (9480-RA) DP (452031) PC

Hello,

Please see the attached bean sheet for PRIA 9480-RA. This was a paper submission. The cover letter, CSFs and other documents are in the CTT drawer.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

## McFarley, Jake

---

**From:** Bain, Zeno  
**Sent:** Tuesday, September 24, 2019 5:51 PM  
**To:** Jean Claude Marcelin  
**Cc:** McFarley, Jake  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Jean Claude

I have checked your website and see that your disinfectants are all named Sani-XXX. Although sanitization is a lower level claim, the name is not preferred because there are different standards for disinfectants vs sanitizers (e.g., contact time) and it can be misleading. I will share this information with the efficacy team to discuss, considering your precedence of having this brand name. At a minimum, "Sani-Diff" (and any names that refer to Diff) would not be allowed because there is not a standard for sanitization for *C. difficile*.

Thank you

Zeno Bain  
Product Manager 33

US Environmental Protection Agency  
Antimicrobials Division (7510P)  
Regulatory Management Branch I  
2777 S. Crystal Drive  
Arlington, VA 22202

ph. 703.347.8102

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 5:31 PM  
**To:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Bain,

This is our Brand name, every single brand in our products portfolio has Sani. For example: Sani-Cloth Plus, Sani-Cloth AF3, Super Sani-Cloth so on and so forth.

Regards,

Jean Claude

**From:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Sent:** Tuesday, September 24, 2019 5:27 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Jean Claude

Every ABN listed on the label has "Sani-XXX" (e.g., Sani-Diff), which can be reasonably interpreted as the product is a sanitizer.

Thank you

Zeno Bain  
Product Manager 33

US Environmental Protection Agency  
Antimicrobials Division (7510P)  
Regulatory Management Branch I  
2777 S. Crystal Drive  
Arlington, VA 22202

ph. 703.347.8102

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 5:24 PM  
**To:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Cc:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Bain,

Can you please tell me where is the Sanitizer reference in the brand name on the Master Label?

Regards,

Jean Claude

**From:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Sent:** Tuesday, September 24, 2019 5:14 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Jean Claude

While I reviewed the label and signed the PD by the deadline, Jake confirmed that we sent the PD to you late, so I apologize for that. However, I still do not have sufficient time to review the label today based on the time I received it. I will point out that the "visibly wet" language has been discussed with you in the past (and we spent a significant amount of time discussing it in the past among several teams) but you continued to negotiate the revision with Jake until very close to the deadline. I will sign the 30-day letter for this action now and Jake will send it to you tomorrow, so that we can complete the label – this is not to say that it will take 30 days but to allow a few more days because it cannot be completed today. I have reviewed most of the label and it appears to be fine but during secondary review (and discussion with Jake and efficacy), we determined that the alternate brand names at the top of the label are unacceptable because any reference to being a sanitizer in the brand name is misleading unless the product is a sanitizer. I am giving you a heads up that Jake will discuss this with you tomorrow via the 30-day letter.

Thank you

Zeno Bain  
Product Manager 33

US Environmental Protection Agency  
Antimicrobials Division (75IOP)  
Regulatory Management Branch I  
2777 S. Crystal Drive  
Arlington, VA 22202

ph. 703.347.8102

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Tuesday, September 24, 2019 3:17 PM  
**To:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Cc:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Bain,

I understand but we did not get the deficiency letter in a timely matter as well. We were supposed to get the letter two weeks before PRIA date but we got the letter last week because I emailed Jake asking for an update that's when he told me he forgot to send the deficiency letter to me. You were copied in all the emails, this is not our fault at all, we just did not get the deficiency letter on time. I think if a mistake was made from a reviewer, we cannot be penalized for that, we need some flexibility as well because we have been very flexible.

Thank!

Jean Claude

**From:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Sent:** Tuesday, September 24, 2019 3:07 PM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Jean Claude

We are nearing the end of the day and have had several rounds of revision on this label. If we don't have an acceptable label by 3:30pm, we will need to complete a 30-day label review letter to account for this deadline. This gives us less than two hours to conduct a complete label review. This will allow you the time to make sure you have addressed all of the comments and we can do one final review. I would appreciate if we can try to be more efficient in the future by reducing the number of back and forth (especially at the deadline) and be more comprehensive with each round of revisions; once you correct one requested edit, we have to complete an entire label review for each version you send us to make sure no other language has changed on the label before approving.

Thank you

Zeno Bain  
Product Manager 33

US Environmental Protection Agency  
Antimicrobials Division (75IOP)  
Regulatory Management Branch I

2777 S. Crystal Drive  
Arlington, VA 22202

ph. 703.347.8102

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 24, 2019 2:50 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jean Claude,

I think you sent over a different version because porous is still in the paragraph at the top of page 10. There should be no 'porous' in the label. It should all be listed as non-porous.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 2:22 PM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Attached are the revised master labels, can you please look at the entire master label and send the final comments?

Thank you!

Jean Claude

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 24, 2019 2:09 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hello Jean Claude,

Please remove the 'porous' from the paragraph at the top of page 10. This product has no efficacy claims for porous. Non-porous use sites only.



Thank you,

Jake

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 1:28 PM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

I removed common on page 13 under general cleaning and deodorizing claims.

Thanks!

Jean Claude

---

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 24, 2019 1:15 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hello Jean Claude,

Please remove 'common' from "household germs". See page 13 for example under general cleaning and deodorizing claims.

Thank you,

Jake

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 12:09 PM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Attached are the revised Master Labels.

Regards,

Jean Claude

---

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 24, 2019 11:34 AM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>

**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hello Jean Claude,

Thank you for sending over the labels.

- Under formula related claims, the bleach free claims must be listed as 'cleaner does not contain [bleach], [alcohol], [quat]'. Otherwise this could be misleading to the user when placed next to the other claims on the label.
- Please note that the table 1 on page 6 still have "May be used on hard, nonporous surfaces" in brackets. Please remove the brackets, remove statement, or change to 'for use on hard, nonporous surfaces in..'
- Table 2 needs to be qualified as hard nonporous.

Thank you,

Jake

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 24, 2019 10:45 AM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Attached are the Master Labels, one clean copy and one highlighted copy with all the revisions we agreed on. Please let me know if you have any additional concerns or comments as soon as possible.

Thank you very much for working with us on this registration.

Jean Claude

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 24, 2019 9:25 AM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Good Morning Jean Claude,

Since the statement 'formula' can be referred to the products pesticidal characteristics this falls under that same category.

Please let me know if you have any other questions.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

---

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Tuesday, September 24, 2019 9:14 AM  
**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Can we say Bleach Free Formula?

Regards,

Jean Claude

---

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Sent:** Tuesday, September 24, 2019 8:52 AM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Good Morning Jean Claude,

I hope that you had a nice weekend.

Thank you for sending these examples over. I understand where you are coming from but many of these claims are not appropriate and should not be on labels. The regulations are clear in regard to this. We are working to rectify this issue. I spoke with Zeno and he confirmed that you can have bleach-free cleaner but not bleach-free antimicrobial of any kind. If you do not agree we will have to issue a 30 day letter. Please let me know by 12:00 pm today. Any further delay will push back this PRIA from being registered.

Please let me know as soon as possible.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

---

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Monday, September 23, 2019 12:45 PM

**To:** Bain, Zeno <Bain.Zeno@epa.gov>

**Cc:** McFarley, Jake <McFarley.Jake@epa.gov>; Jean Claude Marcelin <jmarcelin@pdipdi.com>

**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Bain,

We are about to send you the revised master label but we need clarification on this claim which is very important to the business.

These claims must be removed. Qualifying as cleaners, for example- "Bleach free cleaner" would be allowable. Please refer to Chapter 12 of the Label Review Manual and 40 CFR 156.10 (a)(5).

"These claims are examples of a true statement used in such a way as to give a false or misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained or was not likely to contain in the first place."

We would like to understand why Bleach Free can "give a false or misleading impression to the purchaser" when the product has no Bleach in it.

Below is a list of products currently in the market containing the same type of claims and countless of other consumer products.

**Clorox HP: 67619-25**

- [Chlorine] bleach free
- Does not contain [chlorine] bleach
- Non-[chlorine] bleach

**Clorox VersaSure: 67619**

- Bleach-Free
- Does not -or- doesn't contain] [Chlorine]
- Bleach [Free]
- Non-[chlorine] bleach
- Alcohol-Free
- Clorox Healthcare® VersaCare™ Alcohol-Free Disinfectant Cleaner Wipes (Even allowed in the product name)

**Clorox Fuzion: 67619-30**

- lint-free cloth
- Alcohol free

**Metrex CaviWipes1: 46781-14**

- [Fragrance Free]
- [Bleach-free formula]
- lint-free wipe
- [Free of fragrance]
- [Lead Free]
- [Mercury free]
- [With a bleach free formula]

**Diversey Oxivir 1: 70627**

- Phenol free (No phenols)
- lint-free cloth
- Chlorine free (No (chlorine) (bleach)
- Contains no (abrasives) (bleach) (or harsh acids)
- (No bleach (or chlorine) stains)

- Cleans without bleaching

We feel that the Agency should allow us to make the same type of claims on our products otherwise the Agency will put our Company at a competitive disadvantage when the Agency allowed all our competitors to make a claim and denied us the same claim. This claim stating the product does not contain a specific type of ingredient is only speaking to the type of formula.

Please respond as soon as you possibly can to allow us to send the master label to you today in order to get the PRIA decision tomorrow as scheduled.

Thank you for your prompt feedback!

Jean Claude Marcelin

**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Friday, September 20, 2019 12:38 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hello Jean Claude,

Please see my comments in black below. I understand that there claims on other labels, however please understand that under normal circumstances that we cannot force a company to update their label. The agency can make a note to file and the next time that the registrant submits an application for amendment the changes can be addressed.

1. Visibly wet –Visibly wet is intended for C.difficile directions for use. We do not think this is needed in the non-C.difficile directions for use. Please refer to other competitor products that do not use visibly wet in their contact times for non-C.diff directions for use (EPA Reg. 67619-25, 70627-77). Visibly wet will be present in directions related to C. diff. **I understand that you have discussed this extensively with other Risk Managers and PMs. The agency policy is that this must remain visibly wet for contact time. Please change these as per the pre-decisional letter. Please send me the registration numbers of the products that do not and I will make a note to file for future label changes.**
2. Directions for use (general and C.diff sections)
  - a. We are requesting the option of stating “for contact time listed on the label” instead of stating the actual contact time in the directions for use. This option allows us to have on the product label a table listing each microorganism with their contact times. This table will be placed right next to or below the directions for use on the product label. Our customers have communicated that they find the label easier to understand when the contact times are listed directly next to each microorganism as oppose to when it is listed in the directions for use. **You must remove the brackets from the Disinfecting Directions title and the following paragraph. The contact time must remain in the directions. The other use sites below (ultrasounds transducers, Kills HIV1 etc. ) can refer to the table for contact time. There must be a qualifier for each organism listed that leads to the table.**
3. Sporocidal claims
  - a. PDI wants to use sporocidal since it is a terminology that is commonly used in clinical papers and industry
  - b. Sporocidal is understood to reflect that the product has a disinfection claim against C. diff, for which the testing has been provided for this product-- **The appropriate term for this product is disinfection with sporocidal activity, to substantiate a “sporocidal” claim a product must be tested against both *Bacillus subtilis* and *Clostridium sporogenes*.**

4. Surface material

- a. We are already qualifying the product as hard, nonporous in directions for use, so we don't think it is necessary to add "hard, nonporous" to surface material. **This is fine as long as it is qualified in another section of the label.**

5. Joint Cleaning and Disinfecting Claims

- a. PDI would like to keep joint cleaning and disinfecting claims under the disinfection table since it allows us to make combined cleaning/disinfecting claims. **It is acceptable to keep claims of cleaning and disinfection together; however, the directions for use should have two clear and separate cleaning and disinfection directions.**

6. Bleach/Alcohol/Quat free claims

- a. PDI would like to understand why it is misleading to have these claims. These claims are consistent across the industry. We include because these claims because our customers often ask about ingredients in formula so this is relevant information to provide to them. In addition these claims are there for end users who are looking for specific products that do not have bleach/alcohol/quat. It makes it easy for them to identify these products.
- b. These statements do not make any comparative claims – they only speak to the fact that this product does not have that specific ingredient
- c. All disinfection products (ranging from Clorox Hydrogen Peroxide, Clorox Bleach, Metrex CaviWipes, Metrex Bleach, Diversey Oxivir TB and Diversey Oxivir 1), including PDI's own products make such statements in terms of the type of formula

**These claims must be removed. Qualifying as cleaners, for example- "Bleach free cleaner" would be allowable. Please refer to Chapter 12 of the Label Review Manual and 40 CFR 156.10 (a)(5).**

**"These claims are examples of a true statement used in such a way as to give a false or misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained or was not likely to contain in the first place."**

Please let me know if you have any other questions.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

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**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

**Sent:** Thursday, September 19, 2019 9:52 AM

**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>

**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

**Subject:** RE: Bullet points of PDI's concerns for Flash Wipe master label

Thank you Jake.

Have a gear day!

We will be waiting for your respons

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Sent:** Thursday, September 19, 2019 9:05 AM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Bullet points of PDI's concerns for Flash Wipe master label

Good Morning Jean Claude,

Thank you for sending this over. I confirm receipt. I will be in touch.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Thursday, September 19, 2019 9:02 AM  
**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** FW: Bullet points of PDI's concerns for Flash Wipe master label

Good morning Jake,

Thank you so much for taking our call yesterday to go over your comments with us. We know you are very busy, we greatly appreciate your help. Below is a Mock label showing that we will be listing the contact time on the product label. We also added the bullets we discussed yesterday, please let us know as soon as possible the result of your meeting with your internal team. Please let me know if you need anything else from us.

Regards,

Jean Claude



# Sani-HyPerCide™

GERMICIDAL  
DISPOSABLE WIPE

EXTRA LARGE  
WIPE



BACTERICIDAL, TUBERCULOCIDAL, FUNGICIDAL, AND VIRUCIDAL\* IN 1 MINUTE

## ACTIVE INGREDIENTS:

Hydrogen Peroxide ..... 4.04%

OTHER INGREDIENTS ..... 95.96%

TOTAL ..... 100.00%

Does not include the weight of the wipe.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back panel for additional  
precautionary statements

CONTAINS: 65 Wipes 7.5 x 15 in (19.0 x 38.1 cm)  
Net Wt. 2 lbs 0.11 oz (910.51 g)

**PDI**

REORDER NO. P76584

## Effective against:

Contact time			
1 minute	<b>ANTIBIOTIC RESISTANT BACTERIA</b> Carbapenem Resistant - Klebsiella pneumoniae (CRKP) Acinetobacter baumannii - Multi-Drug Resistant (MDR) Methicillin Resistant Staphylococcus aureus (MRSA) Vancomycin Resistant Enterococcus faecalis (VRE) NDH-1 Positive Enterobacter cloacae ESBL Positive Escherichia coli <b>BACTERIA</b> Salmonella enterica Pseudomonas aeruginosa Staphylococcus aureus <b>BLOODBORNE PATHOGENS</b> Hepatitis B virus (HBV) - Black HAV Hepatitis C virus (HCV) - Same as Hepatitis virus HIV-1 (AIDS virus) <b>NON-ENVELOPED VIRUSES</b> Adenovirus type 6 Rhinovirus type 1a Rotavirus Norovirus (Feline Calicivirus) <b>ENVELOPED VIRUSES</b> Herpes Simplex virus type 2 Influenza A virus (H2N2) / Strain H5N1 Respiratory Syncytial virus (RSV) <b>PATHOGENIC FUNGI</b> Candida albicans Trichophyton interdigitale <td>5 minutes</td> <td> <b>C. DIFFICILE SPORES</b>            Clostridium difficile spores         </td>	5 minutes	<b>C. DIFFICILE SPORES</b> Clostridium difficile spores



1 PDI 031004



(01)00310819008914

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**To Dispense Wipes:** Remove lid and discard inner seal from canister. Find center of roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep center cap of lid closed to prevent moisture loss.

**TO DISINFECT:** Unfold a clean wipe and thoroughly wet surface. Allow treated surface to remain wet for the contact time listed on the label. Let air dry. If present, remove gross filth and heavy soil loads prior to disinfecting. A pre-cleaning step is required to kill *Mycobacterium bovis* BCG (TB) and *Clostridium difficile*. These directions also apply to *Mycobacterium bovis* BCG (TB) at 69.8°F (21°C).

**Precautionary Statements:** Hazards to Humans and Domestic Animals

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**Physical or chemical hazard:** Flammable. Keep away from heat and open flame.

**First Aid:** Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or healthcare professional or going for treatment. For additional information in case of emergency contact the Poison Control Center toll free at 1-800-222-1222.

**If in eye:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage and disposal.

**Storage:** Do not store near heat or open flame. When not in use keep center cap of lid closed to prevent moisture loss. **Towlette Disposal:** Do not reuse towlette.

Dispose of used towlette in trash. Do not flush in toilet. **Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling. If recycling is not available, put in trash collection.

**Optional Use Sites (For complete list, see EPA Master Label):** Ambulances, Bed Railings, Blood glucose monitors, Cabinets, Carts, Chairs, Critical care units (CCU), Dental offices, Dialysis clinics, Emergency rooms, Exam tables, Gurneys, Health care facilities, Hospitals, Intensive care units (ICU), Long term care centers, Nursing Homes, Operating rooms (OR), Patient care areas, Patient rooms, Physical therapy, Physicians' offices, Radiology, Recovery rooms, Rest rooms, Surgical centers, Telephones, Urgent care centers, Workstations on wheels (WOW).

**Surface Materials:** ABS plastic, Aluminum, Brass, Copper, Corian<sup>®</sup>, Chrome, Formica<sup>®</sup>, Glass, Glazed ceramic, Laminate Surfaces, Linoleum, Polycarbonate, Polyester, PVC, Plexiglas<sup>®</sup>, Porcelain, Polybutylene Terephthalate (PBT), Rubber, Stainless Steel, Treated Wood surfaces, Titanium, Vinyl, Zinc.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal protection:** When handling HIV-1 (AIDS virus), HBV or HCV infected blood or body fluids, wear disposable protective gloves, protective gowns, masks and eye coverings, per facility protocol.

**Cleaning procedure:** All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe.

**Disposal of infectious materials:** Used wipe, blood and other body fluids should be disposed of according to local regulation for infectious waste disposal.

**Contact time:** Use second germicidal wipe to thoroughly wet surface. Allow surface to remain wet 1 minute, let air dry.

**Special instructions for cleaning prior to disinfection against *Clostridium difficile* spores:**

**Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks and eye covering.

**Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the sporicidal product. Cleaning is to include (vigorous) wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Waste Disposal:** Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.

**To Disinfect:** Unfold a clean wipe and thoroughly wet surface. Allow surface to remain wet for five (5) minutes. Let air dry.

EPA REG. NO. 9480-JX

EPA EST. NO. 9480-NY-1

<sup>1</sup> Formica<sup>®</sup> is a registered trademark of The Diller Corporation a subsidiary of Formica or one or more of its affiliates.

<sup>2</sup> Corian<sup>®</sup> is a registered trademark of E. I. du Pont de Nemours and Company a subsidiary of E. I. du Pont de Nemours and Company or one or more of its affiliates.

<sup>3</sup> Plexiglas<sup>®</sup> is a registered trademark of Arkema, Inc., a subsidiary of Arkema, Inc., or one or more of its affiliates.

Manufactured by: Professional Disposables International, Inc.

Two Nice-Pak Park, Orangeburg, NY 10962-1376

1-800-999-6423 • Made in USA of Domestic and Imported Materials

80P26501



7. Visibly wet –Visibly wet is intended for C.difficile directions for use. We do not think this is needed in the non-C.difficile directions for use. Please refer to other competitor products that do not use visibly wet in their contact times for non-C.diff directions for use (EPA Reg. 67619-25, 70627-77). Visibly wet will be present in directions related to C. diff
8. Directions for use (general and C.diff sections)
  - a. We are requesting the option of stating “for contact time listed on the label” instead of stating the actual contact time in the directions for use. This option allows us to have on the product label a table listing each microorganism with their contact times. This table will be placed right next to or below the directions for use on the product label. Our customers have communicated that they find the label easier to understand when the contact times are listed directly next to each microorganism as oppose to when it is listed in the directions for use.
9. Sporcidal claims
  - a. PDI wants to use sporicidal since it is a terminology that is commonly used in clinical papers and industry
  - b. Sporcidal is understood to reflect that the product has a disinfection claim against C. diff, for which the testing has been provided for this product

10. Surface material

- a. We are already qualifying the product as hard, nonporous in directions for use, so we don't think it is necessary to add "hard, nonporous" to surface material.

11. Joint Cleaning and Disinfecting Claims

- a. PDI would like to keep joint cleaning and disinfecting claims under the disinfection table since it allows us to make combined cleaning/disinfecting claims.

12. Bleach/Alcohol/Quat free claims

- a. PDI would like to understand why it is misleading to have these claims. These claims are consistent across the industry. We include because these claims because our customers often ask about ingredients in formula so this is relevant information to provide to them. In addition these claims are there for end users who are looking for specific products that do not have bleach/alcohol/quat. It makes it easy for them to identify these products.
- b. These statements do not make any comparative claims – they only speak to the fact that this product does not have that specific ingredient
- c. All disinfection products (ranging from Clorox Hydrogen Peroxide, Clorox Bleach, Metrex CaviWipes, Metrex Bleach, Diversey Oxivir TB and Diversey Oxivir 1), including PDI's own products make such statements in terms of the type of formula

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**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

**Sent:** Wednesday, September 18, 2019 3:33 PM

**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>

**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

**Subject:** RE: 9480-RA Pre-Decisional Letter

You can call me at [REDACTED]

*\*Personal privacy information\**

---

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>

**Sent:** Wednesday, September 18, 2019 2:21 PM

**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jean Claude,

Yes 3:30 PM EST works for me.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Wednesday, September 18, 2019 2:20 PM  
**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Thank you for your reply! I will make the changes and give you a call on the ones we still feel that are questionable or not very clear to us. I would like to give you a call at 3:30pm would that work for you? Please let me know as soon as you can because we would like to resolve the deficiencies as soon as possible.

Thank you for your continuous help on this registration.

Jean Claude

**From:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Sent:** Wednesday, September 18, 2019 2:03 PM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hello Jean Claude,

Thank you for your email. Please note that this is a new PRIA and requires a most recent update to labeling language. When the agency gets label amendment requests from labels that you reference we will review the entire label and based on the deficiencies ask the registrant to make labeling changes. Please let me know of any product labels that have these deficiencies and we can make note to files to have them changed during the next label amendment requests that are submitted.

I tried calling you however you were not in. Do you still want to speak over the phone?

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Wednesday, September 18, 2019 1:41 PM  
**To:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: 9480-RA Pre-Decisional Letter

Hi Jake,

Thank you for sending the Pre-Decision letter to me yesterday!

I am currently working on a response, however a lot of your comments on the languages used on our master label have already been approved on our competitor's labels by the EPA. I would like to have a phone conversation with you to discuss the master label. Please let me know if you will be available to discuss this afternoon.

Thank you for your time!

Jean Claude

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**From:** McFarley, Jake <McFarley.Jake@epa.gov>  
**Sent:** Tuesday, September 17, 2019 1:50 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** 9480-RA Pre-Decisional Letter

Hello Jean Claude,

It appears that this was not sent from my draft messages. Please see the attached. Thank you for your patience.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

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## McFarley, Jake

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, September 17, 2019 12:02 PM  
**To:** McFarley, Jake  
**Cc:** Bain, Zeno  
**Subject:** RE: Project Flash Wipe 9480-RA

Hi Jake,

I just want to reach out to you for an update, the PRIA date is approaching but I have not heard from the EPA yet. We usually get some form of notification 2 weeks prior to approval date asking for clean and highlighted copies of the master label. Can you please give me an update on the above submission?

Thank you!

Jean Claude

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## McFarley, Jake

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**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, June 4, 2019 10:21 AM  
**To:** McFarley, Jake  
**Cc:** Bain, Zeno; Jean Claude Marcelin  
**Subject:** RE: Project Flash Wipe 9480-RA

**Categories:** Completed

Hi Jake,

Thank you very much for taking my call this morning!

Can you please send me the report **DP 440586 (10/10/2017 and 11/30/2017)**? We never received this report from the EPA, if we had the report we would have rerun the study. We were under the impression that EPA had accepted the study, therefore we can bridge the RTU to the Wipes.

Tox monitor provided a letter explaining to the RTU reviewer the chain of events, the Labs thought this issue was settled. Please let us know as soon as possible after you spoke with your team the outcome of the conversion. We really appreciate your understanding and take into consideration the impact on the organization if we would have to repeat that study. This registration was rejected by the Agency because on a minor technicality, we did everything we could possibly do to make sure we complied with all EPA regulations for this submission. We hope that the agency understand that we are not trying to just register a product, we are trying to put the best and most compliant products in the market.

Thank you very much for all your help!

Jean Claude

**From:** McFarley, Jake [mailto:McFarley.Jake@epa.gov]  
**Sent:** Monday, June 03, 2019 5:12 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: Project Flash Wipe 9480-RA

Hello Mr. Marcelin,

I hope that you are doing well. Unfortunately we cannot do such a thing. The PRIA timeline is very strict as it involves multiple teams reviewing a variety of data.

Please note that for the Acute Toxicity, the primary skin irritation study/data provided in MRID 50282507 for the cited product EPA Reg. No. 9480-RU(14) has not been approved under DP 440586 (10/10/2017 and 11/30/2017). You must provide a new primary skin irritation study/data. Please let me know if you have any questions.

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)



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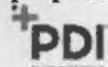
**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Wednesday, May 15, 2019 11:06 AM  
**To:** McFarley, Jake <[McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipe 9480-RA

Good morning Jake,

Can you please let me know who in the Agency I can contact regarding a fast track approval for Project Flash Wipe submitted March 20h, 2019. We would like to know if there is a possibility to pay additional PRIA fees to obtain a fast track. This submission was rejected by the EPA because of a minor technical error in the submission. We invested a lot in the development of this product because we have some customers in the Healthcare industry asking for this product. We would like to get this product in the market as soon as possible because our customers have been asking us for a Hydrogen Peroxide product with *C. difficile* and Norovirus for a while. Please let us know if there is anything the agency can do to help us save at least 2 months in review time, we are fine paying the increased PRIA whatever that may be. Please let me know as soon as possible.

Thank you!

Jean Claude Marcelin  
Sr. Manager, Regulatory Affairs EPA Services  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
P 201-746-8922  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
pdipdi.com



---

**From:** McFarley, Jake [<mailto:McFarley.Jake@epa.gov>]  
**Sent:** Tuesday, May 07, 2019 1:03 PM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** Project Flash Wipe 9480-RA

Hello,

I hope that you are doing well. I am reviewing your PRIA application for product Project Flash Wipe submitted March 20h, 2019. Can you please send over an electronic version of the label?

Thank you,

Jake

Jake McFarley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division  
U.S. Environmental Protection Agency, Office of Pesticide Programs  
(703)347-0123 | [McFarley.Jake@epa.gov](mailto:McFarley.Jake@epa.gov)

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## Regulatory Technical Screen

June 6. ~~December 20, 2019~~

PRIA Code: A540

EPA Registration Number: 9480-RA

Decision Number: 549617

Technical Screen Due Date: 06/10/2019

**21 Day Screen:**Pass: ☒Fail: ☐

Was anything flagged by the front end that should be followed up with the registrant?

No

**Forms Present**

8570-1	Present
Reference Product (Box 6 on the 8570-1 form)	Left Blank but needed
Report of Analysis for Compliance with PR Notice 11-03 (assigned MRIDs and transmittal document)	Absent
Cover Letter	Present
Data Matrix	Present
Label	Present
CSF(s)	Present
Certification with Respect to Data Citation and/or Offer to Pay	Present
Proof of Payment	Present
Formulator's Exemption	Present
Emerging Pathogens Terms and Conditions Letter	Absent
Discipline - How were the data addressed on the Data Matrix	
Product Chemistry	New Study
Acute Toxicology	Not Applicable
Efficacy	New Study
Generic Data	Formulator's Exemption

**Cursory Label/CSF Review**

Active Ingredient	Present
Precautionary Language	Present
First Aid	Present
Storage and Disposal	Absent
Directions for Use	Present
Food Uses	No

EPA Registration Number: 9480-RA  
Decision Number: 549617

Environmental Hazards	Not Applicable
*Are all the inert ingredients cleared?	Yes
*Does the CSF nominal amount match the label?	No

Does the Certification with Respect to Data Match the Data Matrix? Not Applicable

Is this a similar product cited in the 8570-1 or Cover Letter? Substantially Similar/Me Too

What is the registration number of the similar product(s)? 9480-14

Are the application rates consistent with the approved label(s) for this active ingredient?  
Not Applicable

\*Is there a tolerance or a tolerance exemption in place (40 CFR 180)? Not Applicable

\*Are the application rates at or below the tolerance or exemption? Not Applicable

\*Are there any new uses? No

### **Nano**

Is the active ingredient a metal? No

If yes, please continue. If no please skip.

Was particle size information submitted? Choose all that apply.

### **Other**

Is any extra information required to make a regulatory decision? Yes, see below in  
Comments/Notes

Comments/Notes:

This proposed wipe product is bridging data from the spray that it has registered.

\*Can result in a technical screen failure

## McFarley, Jake

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**From:** McFarley, Jake  
**Sent:** Thursday, June 6, 2019 4:43 PM  
**To:** Bain, Zeno  
**Subject:** 9480-RA TS PASSES  
**Attachments:** 9480-RA Regulatory Technical Screen.docx; TS\_AT\_9480-RA\_Project\_DP452098.pdf; Previous AT Review for 9480-14, 9480-RU\_Project\_DP440586\_toxmem\_Dermal.pdf

**Importance:** High

**Categories:** Completed

Hi Zeno,

See the attached regulatory checklist and please note my message to you this morning.

- “I am Also working on the TS Reg checklist for 9480-RA due 06/10/2019
  - This passed efficacy and PC TS. The issue with AT TS is that this is a New PRIA coming in as a wipe, bridging data from an already registered spray product (9480-14). For the pray, the AT review deemed the skin irritation study to be unacceptable however, due to regulatory the AT reviewer for the spray product gave it a tox 3 profile based on regulatory reasons. For the current wipe product the reviewer failed this TS for the reason that we approved the previous based on circumstances. I mentioned this to you a few days ago and you wanted to see correspondence however there seems to be none. “

Have a good weekend,

Jake

## Acute Toxicity Checklist for Technical Screens

FOR INTERNAL USE ONLY

FROM: Boris Yurchak, Chemistry and Toxicology Team, Product Science Branch, Antimicrobials Division

TO: Zeno Bain, PM Team 33 / Jake McFarley

Document date: 6/3/2019

Technical screen due date: 6/3/2019

Reg. No./File Symbol: **9480-RA** DP: 452098

Registrant: Professional Disposables International, Inc

Product: Project Flash Wipes

☐ PASS SCREEN\*

☒ FAIL SCREEN

### I. Administrative documents

Product Label	NOT RECEIVED
CSF	RECEIVED
Cover Letter	RECEIVED
Data Matrix	RECEIVED
Transmittal Document	NOT RECEIVED
Product name consistent throughout submission	YES

### II. Data Requirements

Guideline	Study	Status	Test substance/COA
870.1100	Acute Oral Toxicity	CITED	REGISTERED PRODUCT
870.1200	Acute Dermal Toxicity	CITED	REGISTERED PRODUCT
870.1300	Acute Inhalation Toxicity	CITED	REGISTERED PRODUCT
870.2400	Eye Irritation	CITED	REGISTERED PRODUCT

\* A pass on the technical screen does not indicate that the data will be accepted.

TS\_AT\_9480-RA\_Project\_DP452098.docx

870.2500	Skin Irritation	CITED	REGISTERED PRODUCT
870.2600	Dermal Sensitization	CITED	REGISTERED PRODUCT

III. GLP Conditions

40 CFR 160.12	Signed statement of compliance or non-compliance	N/A
40 CFR 160.35(b) (7)	Statement of QA inspections	N/A
40 CFR 160.1859b}	Study director signature and date	N/A

IV. Additional Information

- a. Rationale has been submitted for all bridging requests: ☐ YES ☐ NO ☒ N/A
- b. Similarity determination:
- i. Cited Product: 9480-14(RU)
  - ii. Proposed product is substantially similar to cited product  
(based on CSFs **only**):
- ☒ YES ☐ NO ☐ N/A

Comments:

1. The registrant has cited all the toxicity data from the EPA Reg, No. 9480-14 to satisfy the acute toxicity data requirements.
2. Proposed label and the transmittal document are missing in the data package.
3. The primary skin irritation study/data provided in MRID 50282507 for the cited product EPA Reg. No. 9480-RU(14) has not been approved under DP 440S86 (10/10/2017 and 11/30/2017). The registrant must provide a new primary skin irritation study/data.

\* A pass on the technical screen does not indicate that the data will be accepted.

TS\_AT\_9480-RA\_Project\_DP452098.docx



### Technical Screen

<b>EPA Reg#/File Symbol:</b> 9480-RA		<b>E-Sub #:</b> N/A	
<b>DP Barcode:</b> 452095		<b>Submission #:</b> 1032956	
<b>Product name:</b> PROJECT FLASH WIPES		<b>Registrant:</b> PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.	
<b>Reviewer's name:</b> Samantha Collins		<b>Risk Manager:</b> Jake McFarley / Zeno Bain	
<b>Completion due date:</b> 06/10/19		<b>Completion Date:</b> 06/05/19	
<b>Formulation type:</b> Liquid <input type="checkbox"/> ; Towelettes <input checked="" type="checkbox"/> ; Spray <input type="checkbox"/> ; Solid <input type="checkbox"/> ; Textile <input type="checkbox"/> ; Aerosol <input type="checkbox"/> ; Other _____			
<b>Sterilant:</b>	<b>Disinfectant:</b> <input checked="" type="checkbox"/>	<b>FC Sanitizer:</b> <input type="checkbox"/>	<b>NF Sanitizer:</b> <input type="checkbox"/>
<b>TB:</b> <input checked="" type="checkbox"/>		<b>Fungicidal:</b> <input checked="" type="checkbox"/>	
<b>Virucide:</b> <input checked="" type="checkbox"/>			
<b>MRID(s):</b> 50828802, 50828803, 50828804, 50828805, 50828806, 50828807, 50828808, 50828809, 50828810, 50828811, 50828812, 50828813, 50828814, 50828815, 50828816, 50828817, 50828818, 50828819, 50828820, 50667311, 50667312			
000595	Hydrogen Peroxide	4.04%	3.85%
<b>Label Claims:</b> Disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, sporicidal) ready to use towelette product for hard, non-porous surfaces at a 1-minute disinfectant contact time and 5-minute sporicidal contact time with a 5% organic soil load present (100% duck serum for Duck Hepatitis 8 virus and 500-µL final test suspension for disinfectants with sporicidal activity).			
PDI-0032-0022-A	3.80%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0032-0023-A	3.79%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0032-0024-A	3.82%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-032-067A	3.93%	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
PDI-032-068A	3.93%	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
PDI-0061-LO-938-146-A	3.86%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-146-B	3.86%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-146-C	3.86%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-1003-150-A	3.82%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-1003-151-A	3.84%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-1003-152-A	3.83%	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<b>Tested:</b> RTU <input checked="" type="checkbox"/> Diluted <input type="checkbox"/>		<b>Tested Dilution Rate:</b> RTU	
<b>Certificate of Analysis:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		<b>Performed by testing Lab:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
<b>Test Lab:</b> Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, VA 20164			

**Comments: Efficacy Review:**

Submitted data to support bactericidal disinfection claims for a towelette product with a 5% soil load present, at a 1-minute contact time against: *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606), Extended spectrum  $\beta$ -lactamase (ESBL) *Escherichia coli* (ATCC BAA-196), Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592), NDM-1-Positive *Enterobacter cloacae* [CDC strain 1000654] (ATCC BAA-2468), and Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)

Submitted data to support virucidal disinfection claims for a towelette product with a 5% soil load present (100% duck serum for Duck Hepatitis 8 virus), at a 1-minute contact time against: Adenovirus Type 5, Strain: Adenoid 75, ATCC VR-5, Rhinovirus Type 1A, Strain: 2060, ATCC VR-1559, Human Rotavirus, Strain: WA, ATCC VR-2018, Herpes Simplex Virus Type 2, Strain: G, ATCC VR-734, Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68, Charles River Laboratories, Respiratory Syncytial Virus, Strain: Long, ATCC VR-26, Feline calicivirus, Strain: F9, ATCC VR-782 (surrogate for Human Norovirus), Duck Hepatitis 8 Virus, Strain: Grimaud, HepadnaVirus Testing, Inc. (surrogate for Human Hepatitis B virus), and Human Immunodeficiency Virus Type 1, Strain: IIIB, ZeptoMetrix

Submitted data to support Tuberculocidal disinfection claims for a towelette product with a 5% soil load present, at a 1-minute contact time against: *Mycobacterium bovis* (ATCC 35743)

Submitted data to support fungicidal disinfection claims for a towelette product with a 5% soil load present, at a 1-minute contact time against: *Trichophyton mentagrophytes* (ATCC 9533), and *Candida albicans* (ATCC 10231)

Submitted data to support disinfectant with sporicidal activity claims for a towelette product with a 500- $\mu$ L final test suspension (340  $\mu$ L spore suspension, 25  $\mu$ L BSA, 100  $\mu$ L Mucin, 35  $\mu$ L of yeast Extract) load present, at a 5-minute contact time against: *Clostridium difficile* (a toxigenic strain - tcdA-, tcdB+) (ATCC 43598)

Product is cleared for technical screen

## **McFarley, Jake**

---

**From:** Alekseyev, Sergey  
**Sent:** Thursday, May 16, 2019 7:00 AM  
**To:** McFarley, Jake  
**Cc:** Hicks, Karen  
**Subject:** TechScreen for reg. no. 9480-RA, DP 452031

People, TS for this product is OK.

Regards,  
Sergey Alekseyev  
Chemist  
S-8831  
308 8167



INTERVENTIONAL CARE

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400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
pdihc.com

March 20, 2019

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive, Room S-4900  
Arlington VA 22202

Attn: Zeno Bain, PM 33  
Product: Project Flash Wipes  
EPA Reg. No: 9480-  
Company: Professional Disposables International, Inc.

Dear Mr. Bain:

This letter is a request to add Emerging Viral Pathogen Claims statements to the Project Flash Wipes master label in accordance with ***EPA's 2016 Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels***. Our Project Flash Wipes is qualified to be eligible to meet the emerging pathogen guidance criteria because of the claims against the following viruses:

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	<b>One</b> of the following: Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	<b>One</b> of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	<b>Two</b> of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

**ABOUT PDI**

At PDI, we never forget who we are all working for. That's why we offer a broad range of evidence-based, market leading Interventional Care, Environment of Care, and Patient Care solutions, all designed to help reduce preventable infections, control healthcare costs, and ultimately help save lives. It's all part of our passion to *Be The Difference*®, every day. To learn more, visit [www.pdihc.com](http://www.pdihc.com).

1. The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Statements shall adhere to one or both of the following formats:

**[Product name]** has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[porous and/or non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

**[Name of illness/outbreak]** is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

3. The registrant may begin communicating these statement(s) upon notification on the CDC or OIE website identified under Section V of the Guidance of an outbreak of an emerging **[small non-enveloped, large non-enveloped, and/or enveloped]** viral pathogen. The registrant shall cease and remove all such non-label communications intended for consumers no later than 24 months after the original notification of the outbreak on the CDC or OIE website, unless the agency provides guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **[name of supporting virus(es)]** is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

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If you have any questions, please contact me at [jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com) or (201) 746-8922

Sincerely,

**Jean Claude Marcelin**

Sr. Manager, Regulatory Affairs EPA Services  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
Ph. 201-746-8922

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**Transmittal Document****Submitter:****Professional Disposables International, Inc. (PDI)**400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677**Company Contact:****Jean Claude Marcelin**

Sr. Manager, Regulatory Affairs EPA Services

**Regulatory action in support of which this package is submitted:**

Application for registration of Project Flash Wipes

**Submission Date:****March 20, 2019****Submitted Studies:**

- 50628801 • Volume 1: Product identity, Manufacturing Process, and Enforcement Analytical Method
- 50828802 • Volume 2: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Staphylococcus aureus
- 50828803 • Volume 3: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Pseudomonas aeruginosa
- 50828804 • Volume 4: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Salmonella enterica
- 50828805 • Volume 5: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Multi-Drug Resistant (MDR) Acinetobacter baumannii
- 50828806 • Volume 6: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Extended spectrum  $\beta$ -lactamase (ESBL) Escherichia coli
- 50828807 • Volume 7: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Methicillin-Resistant Staphylococcus aureus (MRSA)
- 50828808 • Volume 8: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: NDM-1 Positive Enterobacter cloacae
- 50828809 • Volume 9: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Vancomycin Resistant Enterococcus faecalis (VRE)
- 50828810 • Volume 10: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Adenovirus Type 5
- 50828811 • Volume 11: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Rhinovirus Type 1A
- 50828812 • Volume 12: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Rotavirus
- 50828813 • Volume 13: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Herpes Simplex Virus Type 2
- 50828814 • Volume 14: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Influenza A Virus (H3N2)
- 50828815 • Volume 15: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Respiratory Syncytial Virus (RSV)
- 50828816 • Volume 16: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Feline calicivirus (Surrogate for Human Norovirus)



- 50828817 • Volume 17: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)
- 50828818 • Volume 18: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Immunodeficiency Virus Type 1 (HIV-1)
- 50828819 • Volume 19: Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness: Mycobacterium bovis
- 50828820 • Volume 20: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Candida albicans



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March 20, 2018

For Efficacy  
been

U.S. Environmental Protection Agency  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
1200 Pennsylvania Avenue, N.W.  
Washington DC 20460-0001

Attn: Zeno Bain, PM 33

**Re: Application for New Registration: Project Flash Wipes**

**PRIA Fee Category: A540 (receipt attached to application form); Decision time: 5 months;**

**Fees: \$5,107**

Product is based on the EPA Reg. No. 9480-14, Project Flash Spray

**Company: Professional Disposables International, Inc. (PDI)**

**Product Name: Project Flash Wipes**

**File Symbol: 9480-**

Dear Mr. Bain,

I am submitting this application for a new end-use registration for the product, Project Flash Wipes (EPA Reg. No. 9480- ). PDI previously submitted this application to the agency on August 22, 2018. However, the application was withdrawn on November 29, 2018 due to efficacy technical screen failure. PDI has resolved these discrepancies by including new efficacy studies in this package and an explanation on the *Clostridium difficile* spore data below.

Project Flash Wipes is a disinfectant wipe for hard, nonporous, non-food contact surfaces. Certain data requirements are being bridged from our already registered product, Project Flash Spray (EPA Reg No. 9480-14).

#### **PRIA**

This product is in PRIA Fee Category A540, \$5,107 fee paid in advance (receipt attached to application form) 5 months' time frame. The product formulation and label are substantially similar to Project Flash Spray (EPA Reg. No. 9480-14). This product contains an active ingredient and uses included in other EPA registered end use products.

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### CSF

The product is a hard surface, broad spectrum, hospital disinfectant. With the exception of the towelette material, the formulation is identical to Project Flash Spray (EPA Reg. No. 9480-14).

The towelette product uses the same EPA registered sources of active ingredient and EPA listed inert ingredients as the spray product. In addition, the same suppliers for the active and inert ingredients are used for the towelette product.

### Label

The towelette label is substantially similar to the Project Flash Spray label. It also has a five (5) minute contact time for *C.difficile* spore and one (1) minute for all other organisms. The optional towelette claims are similar to claims found on other EPA approved PDI wipe product labels.

The towelette label contains Pandemic 2009 H1N1 Influenza A virus claims on pages 11& 12. These claims are in accordance with the October 22, 2009 *Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)*. During the registration review of our Project Flash Spray (9480-14), EPA requested that we remove these Pandemic claims, as we did not conduct efficacy test against this microorganism. For Project Flash Wipes, we believe, that we should be allowed to have these claims on the label as the following disinfectant towelettes on the market also have these claims on their most current EPA accepted master labels:

- Accel TB Wipes, EPA Reg. No. 74559-3 (November 16, 2018)
- CPPC Tsunami, EPA Reg. No. 67619-12 (February 14, 2018)
- Elf, EPA Reg. No. 67619-37 (March 8, 2018)

All of these product master labels have recently been reviewed and accepted in 2018.

### Toxicity Data on End Use

We are citing all of the toxicity data from the 9480-14. The 9480-14 liquid is used in Project Flash Wipes with only the wipe material being different. Please see MRIDs for these studies on the end use data matrix.

### Chemistry Data on End Use

As per EPA's guidance on towelettes, we are including characterization information on the wipe liquid. In addition, we are citing MRIDs for the chemistry data that was provided for the initial submission of Project Flash Wipes on August 22, 2018. Please see MRIDs for the studies on the end use data matrix.

#### ABOUT PDI

At PDI, we never forget who we are all working for. That's why we offer a broad range of evidence-based, market leading Interventional Care, Environment of Care, and Patient Care solutions, all designed to help reduce preventable infections, control healthcare costs, and ultimately help save lives. It's all part of our passion to Be The Difference®, every day. To learn more, visit [www.pdihc.com](http://www.pdihc.com).



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400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
pdihc.com

### Efficacy Data

For this towelette product registration, we are submitting the full complement of efficacy studies. There will be no bridging of efficacy data from Project Flash Spray (EPA Reg. No 9480-14). Nineteen (19) new efficacy studies and four (4) previously submitted towelette efficacy data are cited for the following organisms: Carbapenem Resistant-*Klebsiella pneumoniae*, Hepatitis C Virus (Human) (HCV), *Trichophyton mentagrophytes* and *Clostridium difficile* spores. Please see MRIDs for these four (4) studies on the end use data matrix.

### Clarification of Test Product lot analysis used in *Clostridium difficile* spore Studies (MRID No. 50667312)

As mentioned above, Project Flash Wipes was previously submitted to the agency and withdrawn due to an efficacy technical screen failure. In a technical screen failure letter dated October 25, 2018 and an email correspondence from the agency dated November 13, 2018, the EPA efficacy reviewer indicated that the active ingredient (AI) analysis of Lot PDI-0061-LO-1003-150A used in the *Clostridium difficile* spore study (MRID 50667312) was conducted after the efficacy study was performed. However, after an internal review of this C.diff study and accompanying CoA, we have concluded that the efficacy study was performed after the AI analysis was done. The CoA was issued on 22 May 2018 and the efficacy study followed thereafter on 31 May 2018. Based on the AI analysis being conducted prior to the start of the efficacy study, the *Clostridium difficile* spore study meets the criteria for acceptance per the Agency's requirements. A copy of the technical screen failure letter, the agency's email correspondence, and PDI's responses to both communications have been included in this submission for your reference.

### Enclosures

The following documents are enclosed in support of this application:

- EPA form 8570-1
- Receipt to show payment of PRIA fee (attached to application)
- Efficacy technical screen failure letter dated 10/25/18 and PDI's response letter dated 11/1/18
- Agency's email correspondence dated 11/13/18 and PDI's response letter dated 11/14/18
- Certification with respect to Citation of Data
- End Use Data Matrix – Internal and External Copies
- Formulator's Exemption Statement
- Confidential Statement of Formula: Basic and Alt.#1 (2 copies each)
- Emerging Viral Pathogen Request Letter
- Five copies of label
- Three sets of 20 study volumes listed in attached transmittal

### ABOUT PDI

At PDI, we never forget who we are all working for. That's why we offer a broad range of evidence-based, market leading Interventional Care, Environment of Care, and Patient Care solutions, all designed to help reduce preventable infections, control healthcare costs, and ultimately help save lives. It's all part of our passion to Be The Difference®, every day. To learn more, visit [www.pdihc.com](http://www.pdihc.com).



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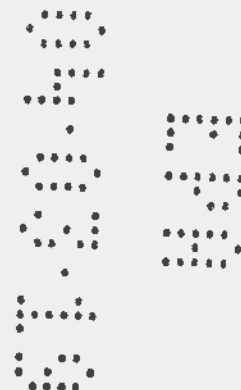
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
pdihc.com

If you have any questions, please contact me at [jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com) or (201) 746-8922

Sincerely,

**Jean Claude Marcelin**

Sr. Regulatory Affairs Manager, EPA Services  
Professional Disposables International, Inc. (PDI)  
400 Chestnut Ridge Road  
Woodcliff Lake, NJ 07677  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
Ph. 201-746-8922



#### ABOUT PDI

At PDI, we never forget who we are all working for. That's why we offer a broad range of evidence-based, market leading interventional Care, Environment of Care, and Patient Care solutions, all designed to help reduce preventable infections, control healthcare costs, and ultimately help save lives. It's all part of our passion to *Be The Difference®* every day. To learn more, visit [www.pdihc.com](http://www.pdihc.com).

*\*Product ingredient source information may be entitled to confidential treatment\**

\*Inert ingredient information may be entitled to confidential treatment\*

## Transmittal Document

### Submitter:

**Professional Disposables International, Inc. (PDI)**

400 Chestnut Ridge Road

Woodcliff Lake, NJ 07677

### Company Contact:

**Jean Claude Marcelin**

Sr. Manager, Regulatory Affairs EPA Services

### Regulatory action in support of which this package is submitted:

Application for registration of Project Flash Wipes

### Submission Date:

**March 20, 2019**

### Submitted Studies:

- Volume 1: Product identity, Manufacturing Process, and Enforcement Analytical Method
- Volume 2: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: *Staphylococcus aureus*
- Volume 3: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: *Pseudomonas aeruginosa*
- Volume 4: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: *Salmonella enterica*
- Volume 5: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Multi-Drug Resistant (MDR) *Acinetobacter baumannii*
- Volume 6: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Extended spectrum  $\beta$ -lactamase (ESBL) *Escherichia coli*
- Volume 7: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Methicillin-Resistant *Staphylococcus aureus* (MRSA)
- Volume 8: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: NDM-1 Positive *Enterobacter cloacae*
- Volume 9: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Vancomycin Resistant *Enterococcus faecalis* (VRE)
- Volume 10: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Adenovirus Type 5
- Volume 11: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Rhinovirus Type 1A
- Volume 12: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Rotavirus
- Volume 13: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Herpes Simplex Virus Type 2
- Volume 14: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Influenza A Virus (H3N2)
- Volume 15: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Respiratory Syncytial Virus (RSV)
- Volume 16: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Feline calicivirus (Surrogate for Human Norovirus)



- Volume 17: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)
- Volume 18: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Immunodeficiency Virus Type 1 (HIV-1)
- Volume 19: Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness: *Mycobacterium bovis*
- Volume 20: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: *Candida albicans*



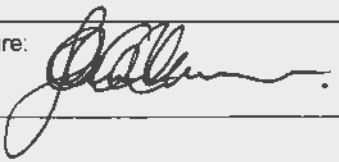
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0080

**END-USE DATA MATRIX**

Date: March 20, 2019		EPA Reg. No./File Symbol: 9480-		Page 1 of 6	
Applicant's/Registrant's Name & Address: <b>Professional Disposables International, Inc. (PDI) 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677</b>		Product:  <b>Project Flash Wipes</b>			
Ingredient(s): <b>Hydrogen Peroxide 36%</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

830.1550	Product identity and composition	To be assigned 50282501	PDI	OWN	
830.1600	Description of materials used to produce the product	To be assigned 50282501	PDI	OWN	
830.1620	Description of production process	To be assigned 50282501	PDI	OWN	
830.1650	Description of formulation process	To be assigned 50282501	PDI	OWN	
830.1670	Discussion of formulation of impurities	To be assigned 50282501	PDI	OWN	
830.1700	Preliminary analysis	To be assigned 50282501	PDI	OWN	
830.1750	Certified limits	To be assigned 50282501	PDI	OWN	
830.1800	Enforcement analytical method	50282501	PDI	OWN	
830.1900	Submittal of Samples	N/A	N/A	N/A	Available Upon Request
830.6302	Color	50667302 50282502 50356601	PDI	OWN	

Signature: 	Name & Title: Jean Claude Marcelin, Sr. Manager, Regulatory Affairs EPA Services	Date: March 20, 2019
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**END-USE DATA MATRIX**

Date: March 20, 2019	EPA Reg. No./File Symbol: 9480-	Page 2 of 6
Applicant's/Registrant's Name & Address: <b>Professional Disposables International, Inc. (PDI) 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677</b>	Product: <b>Project Flash Wipes</b>	

Ingredient(s): **Hydrogen Peroxide 35%**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical state	50667302 50282502 50356601	PDI	OWN	
830.6304	Odor	50667302 50282502 50356601	PDI	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	50667302 50356601	PDI	OWN	
830.6315	Flammability	50667302 50282502 50356601	PDI	OWN	
830.6316	Explosibility	50667302 50282502 50356601	PDI	OWN	
830.6317	Storage stability	50667302 50356601	PDI	OWN	
830.6319	Miscibility	50667302 50282502 50356601	PDI	OWN	
830.6320	Corrosion characteristics	50667302 50356601	PDI	OWN	
830.6321	Dielectric breakdown voltage	50667302 50282502 50356601	PDI	OWN	

Signature: 	Name & Title: Jean Claude Marcelin, Sr. Manager, Regulatory Affairs EPA Services	Date: March 20, 2019
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**END-USE DATA MATRIX**

Date: March 20, 2019		EPA Reg. No./File Symbol: 9480-	Page 3 of 6		
Applicant's/Registrant's Name & Address: <b>Professional Disposables International, Inc. (PDI) 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677</b>		Product: <b>Project Flash Wipes</b>			
Ingredient(s): <b>Hydrogen Peroxide 35%</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

830.7000	pH	50667302 50356601	PDI	OWN	
830.7100	Viscosity	50667302 50282502 50356601	PDI	OWN	
830.7300	Relative Density	50667302 50282502 50356601	PDI	OWN	
870.1100	Acute Oral Toxicity Study in Rats	50282503	PDI	OWN	
870.1200	Acute Dermal Toxicity Study in Rabbits	50282504	PDI	OWN	
870.1300	Acute Inhalation Toxicity Study in Rats	50282505	PDI	OWN	
870.2400	Acute Eye Irritation Study in Rabbits	50282506	PDI	OWN	
870.2500	Acute Dermal Irritation Study in Rabbits	50282507	PDI	OWN	
870.2600	Skin Sensitization Study in Guinea Pigs	50282508	PDI	OWN	

Signature: 	Name & Title: Jean Claude Marcelin, Sr. Manager, Regulatory Affairs EPA Services	Date: March 20, 2019
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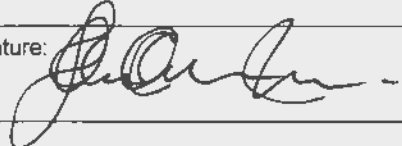
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**END-USE DATA MATRIX**

Date: March 20, 2019		EPA Reg. No./File Symbol: 9480-	Page 4 of 6	
Applicant's/Registrant's Name & Address: <b>Professional Disposables International, Inc. (PDI) 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677</b>		Product: <b>Project Flash Wipes</b>		
Ingredient(s): <b>Hydrogen Peroxide 35%</b>				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
				Note

810.2200	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection : Staphylococcus aureus	To be assigned	PDI	OWN	Vol 2
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Pseudomonas aeruginosa	To be assigned	PDI	OWN	Vol 3
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Salmonella enterica	To be assigned	PDI	OWN	Vol 4
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Multi-Drug Resistant (MDR) Acinetobacter baumannii	To be assigned	PDI	OWN	Vol 5
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Supplemental: Carbapenem-Resistant Klebsiella pneumoniae	50667306	PDI	OWN	
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Additional Organism: Extended spectrum $\beta$ -lactamase (ESBL) Escherichia coli	To be assigned	PDI	OWN	Vol 6
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Methicillin-Resistant Staphylococcus aureus (MRSA)	To be assigned	PDI	OWN	Vol 7
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: NDM-1 Positive Enterobacter cloacae	To be assigned	PDI	OWN	Vol 8
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Vancomycin Resistant Enterococcus faecalis (VRE)	To be assigned	PDI	OWN	Vol 9

Signature: 	Name & Title: Jean Claude Marcelin; Sr. Manager, Regulatory Affairs EPA Services	Date: March 20, 2019
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0080

**END-USE DATA MATRIX**

Date: March 20, 2019

EPA Reg. No./File Symbol: 9480-

Page 5 of 6

Applicant's/Registrant's Name & Address:

**Professional Disposables International, Inc. (PDI)  
400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677**

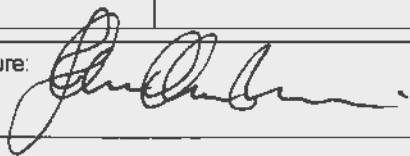
Product:

**Project Flash Wipes**

Ingredient(s): **Hydrogen Peroxide 35%**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Adenovirus Type 5	To be assigned	PDI	OWN	Vol 10
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Rhinovirus Type 1A	To be assigned	PDI	OWN	Vol 11
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Rotavirus	To be assigned	PDI	OWN	Vol 12
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Herpes Simplex Virus Type 2	To be assigned	PDI	OWN	Vol 13
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Influenza A Virus (H3N2)	To be assigned	PDI	OWN	Vol 14
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Respiratory Syncytial Virus (RSV)	To be assigned	PDI	OWN	Vol 15
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Feline calicivirus (Surrogate for Human Norovirus)	To be assigned	PDI	OWN	Vol 16
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)	To be assigned	PDI	OWN	Vol 17
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Bovine Viral Diarrhea Virus (Surrogate for Human Hepatitis C Virus)	50667310	PDI	OWN	
	Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test: Human Immunodeficiency Virus Type 1 (HIV-1)	To be assigned	PDI	OWN	Vol 18
	Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness: Mycobacterium bovis	To be assigned	PDI	OWN	Vol 19
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection: Trichophyton mentagrophytes	50667311	PDI	OWN	

Signature:



Name & Title:

Jean Claude Marcelin, Sr. Manager, Regulatory Affairs EPA Services

Date:

March 20, 2019

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**END-USE DATA MATRIX**

Date: March 20, 2019

EPA Reg. No./File Symbol: 9480-

Page 6 of 6

Applicant's/Registrant's Name & Address:

**Professional Disposables International, Inc. (PDI)  
400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677**

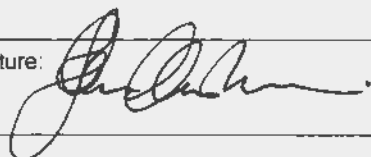
Product:

**Project Flash Wipes**

Ingredient(s): **Hydrogen Peroxide 35%**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism: Candida albicans	To be assigned	PDI	OWN	Vol 20
	OECD Quantitative Method for Testing Antimicrobial Products Against Spores of Clostridium difficile on Inanimate, Hard, Non-Porous Surfaces GLP	50667312	PDI	OWN	
	OECD Quantitative Method for Testing Antimicrobial Products Against Spores of Clostridium difficile on Inanimate, Hard, Non-Porous Surfaces GLP	50667312	PDI	OWN	
	OECD Quantitative Method for Testing Antimicrobial Products Against Spores of Clostridium difficile on Inanimate, Hard, Non-Porous Surfaces GLP	50667312	PDI	OWN	

Signature:



Name & Title:

Jean Claude Marcelin, Sr. Manager, Regulatory Affairs EPA Services

Date:

March 20, 2019





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 25, 2018

Jean Claude Marcelin  
Manager  
Regulatory Affairs  
Professional Disposables International, PDI  
Two Nice-Pak Park  
Orangeburg, NY 10962

Subject: Technical Screen Failure  
Product Name: Project Flash Wipes  
EPA File Symbol: 9480-RL  
Application Date: 08/22/2018  
Decision Number: 543820

Dear Mr. Marcelin:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

The Certificate of Analyses (CoAs) must be generated before efficacy testing.

Lots PDI-0061-LO-938-146-A, PDI-0061-LO-938-146-B, and PDI-0061-LO-938-146-C were tested for AI concentrations, according to the provided certificate of analysis, 16 days after they have been used in efficacy studies against *S. aureus*, *S. enterica*, *P. aeruginosa*; 7 days after *M. bovis*; and 3 days after Adenovirus Type 5.

Lots PDI-0061-LO-938-142A and PDI-0061-LO-938-142B, were tested for AI concentrations, according to the provided certificate of analysis, 21 days after they have been used in the efficacy study against Feline Calicivirus.

Lots PDI-0061-LO-1003-150-A was tested for AI concentration, according to the provided certificate of analysis, 20 days after being used in the efficacy study against spores of *Clostridium difficile*.

In order for the review of your pesticide product to continue, you will need to correct your application to address the items listed above within 10 business days of the date you received this letter. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being

for reference  
previously withdrawn  
application

Page 2 of 2  
EPA File Symbol 9480-RL  
Decision No. 543820

submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

Sincerely,



Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Efficacy Technical Screen Memo

## Technical Screen

<b>EPA Reg#/File Symbol:</b> 9480-RL		<b>E-Sub #:</b>	
<b>DP Barcode:</b> 448850		<b>Submission #:</b> 1024080	
<b>Product name:</b> Project Flash Wipes		<b>Registrant:</b> Professional Disposables International Inc.	
<b>Reviewer's name:</b> Ibrahim Laniyan		<b>Risk Manager:</b> Zeno Bain RM 33 / Aline Heffernan	
<b>Completion due date:</b> 10/25/2018		<b>Completion Date:</b> 10/24/2018	
<b>Formulation type:</b> Liquid <input type="checkbox"/> ; Towelettes <input checked="" type="checkbox"/> ; Spray <input type="checkbox"/> ; Solid <input type="checkbox"/> ; Textile <input type="checkbox"/> ; Aerosol <input type="checkbox"/> ; Gas <input type="checkbox"/> ; Other <input type="checkbox"/>			
Sterilant: <input type="checkbox"/> Disinfectant: <input checked="" type="checkbox"/> FC Sanitizer: <input type="checkbox"/> NF Sanitizer <input type="checkbox"/> TB: <input checked="" type="checkbox"/> Fungicidal: <input checked="" type="checkbox"/> Virucidal: <input checked="" type="checkbox"/>			
<b>MRID(s):</b> 50667303, 50667304, 50667305, 50667306, 50667307, 50667308, 50667309, 50667310, 50667311, 50667312.			
<b>PC Code(s)</b>	<b>Active Ingredient Names</b>	<b>% wt (label)</b>	<b>%LCL (Acceptable)</b>
000595	Hydrogen peroxide	4.04	3.838 (3.87638)
<b>Label Claims:</b> RTU      CT (1 min., 5 min.)			
<b>Product Lot(s)</b>	<b>Tested Concentration(s)</b>	<b>Tested at LCL</b>	
PDI-0061-LO-938-146-A	3.86% Hydrogen Peroxide (04-08-16 but tested on 3-23-16)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-146-B	3.86% Hydrogen Peroxide (04-08-16 but tested on 3-23-16)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-146-C	3.87% Hydrogen Peroxide (04-08-16 but tested on 3-23-16)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-142A	3.74% Hydrogen Peroxide (04-08-16 but tested on 3-18-16)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-938-142B	3.73% Hydrogen Peroxide (04-08-16 but tested on 3-18-16)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-1003-150-A	3.69% Hydrogen Peroxide (06-20-18 but tested on 05-31-18)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PDI-0061-LO-1003-151-A	3.68% Hydrogen Peroxide	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<b>Tested:</b> RTU <input checked="" type="checkbox"/> Diluted <input type="checkbox"/> CT (1 min., 5 min.)		<b>Tested Dilution Rate:</b> N/A	
<b>Certificate of Analysis:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		<b>Performed by testing Lab:</b> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
<b>Test Lab:</b> Microbac		<b>ATP Cleared:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Comments:</b> Efficacy Review			
<p><b>Product is not cleared for Technical Screen.</b></p> <p>PDI-0061-LO-938-146-A, PDI-0061-LO-938-146-B, and PDI-0061-LO-938-146-C were tested for AI concentrations, according to the provided certificate of analysis, <b>16 days</b> after they have been used in efficacy studies against <i>S. aureus</i>, <i>S. enterica</i>, <i>P. aeruginosa</i>; <b>7 days</b> after <i>M. bovis</i>; and <b>3 days</b> after Adenovirus Type 5.</p> <p>PDI-0061-LO-938-142A and PDI-0061-LO-938-142B, were tested for AI concentrations, according to the provided certificate of analysis, <b>21 days</b> after they have been used in the efficacy study against Feline Calicivirus.</p> <p>PDI-0061-LO-1003-150-A was tested for AI concentration, according to the provided certificate of analysis, <b>20 days</b> after being used in the efficacy study against spores of <i>Clostridium difficile</i>.</p>			



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Aline Heffernan  
U.S. Environmental Protection Agency  
Regulatory Management Branch I  
Antimicrobial Division (7510P)  
Office of Pesticide Programs

November 1, 2018

Subject: Technical Screen Failure  
Product Name: Project Flash Wipes  
EPA File Symbol: 9480-RL  
Application Date: 08/22/18  
Decision Number: 543820 – Memo Dated 10/25/18  
PRIA Decision Date: February 19, 2019

Dear Ms. Heffernan,

PDI would like to thank you for completing the preliminary technical screening of our application for Project Flash Wipes.

We would like to address the items noted in your memo dated 25 Oct. 2018, with a response to these findings. According to EPA's review, the analyses of the AI concentrations for several of the test product Lots provided in CoA's were conducted after the initiation of the efficacy studies.

**RE: Lot# PDI-0061-LO-1003-150-A - used in *Clostridium difficile* spore study MRID 50667312**

In the memo, EPA has indicated that the AI analysis of Lot **PDI-0061-LO-1003-150-A** was conducted after the efficacy study was performed. Based on PDI's internal review of the study MRID 50667312 and accompanying CoA, we have concluded that the efficacy study was performed after the AI analysis was done. The CoA was issued on 22 May 2016 and the efficacy study followed thereafter on 31 May 2016. Based on this, the study meets the criteria for acceptance as per the Agency's requirements.

**RE: Lot #'s PDI-0061-LO-938-142-A, PDI-0061-LO-938-142-B, PDI-0061-LO-938-146-A, PDI-0061-LO-938-146-B and PDI-0061-LO-938-146-C**

PDI has reviewed the CoA's for **Lot #'s PDI-0061-LO-938-142-A, PDI-0061-LO-938-142-B** used in the efficacy study against Feline Calicivirus, and **Lot #'s PDI-0061-LO-938-146-A, PDI-0061-LO-938-146-B and PDI-0061-LO-938-146-C** used in the efficacy studies against *S. aureus*, *P. aeruginosa*, *S. enterica*, *M. bovis* and Adenovirus Type 5 and would like to provide an explanation of the discrepancy.

- PDI's routine process is for R&D to prepare the required lots of test product at the required active ingredient (AI) concentration (e.g., LCL or Nominal) for the organism desired. Once the lots have been analyzed, the CoA is prepared.
- The CoA is sent along with the test product lots to the external efficacy testing laboratory.
- Efficacy studies are conducted once the test products and protocols are at the testing lab.

Regarding the test product lots in question, it was our understanding that the date that each CoA was created, i.e., 3/17/16, was also the date that the AI analyses were conducted. This date precedes all of the scheduled efficacy study dates. It was an oversight that the AI analyses were actually conducted on 4/8/16 as indicated in the CoA's included in the final reports, as this is not our routine process.

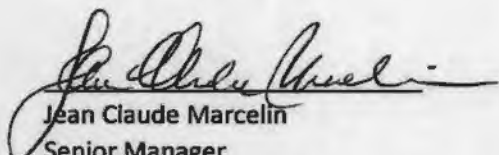
PDI R&D and Regulatory Affairs departments have since revised its internal preparation and tracking processes for future studies to avoid this from recurring.

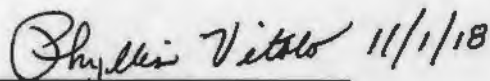
We hope this appropriately explains the discrepancy observed during technical review and the agency continues with the review process. Please also take into consideration that three lots (MRID 50667312) of the Project Flash Wipes formulation were prepared at the LCL active concentration and passed against *C. difficile* spores, the hardest to kill, proposed disinfectant claim. The bacterial and viral organisms used in the efficacy studies in question are all ranked lower than *C. difficile* spores in their difficulty to kill under the premise of disinfectant hierarchy of pathogens.

The PRIA date for Project Flash Wipes is February 19, 2019. In the event that your decision is to discontinue the review of the application as currently presented, we would like to request the opportunity to repeat new efficacy studies within the next four months. We respectfully request a one (1) month extension beyond the PRIA date which would allow completion of the new studies, including the *M. bovis* tuberculocidal test requirement of 115 days.

Thank you for your time and consideration.

Sincerely,

  
Jean Claude Marcelin  
Senior Manager  
PDI Regulatory Affairs

 11/1/18  
Phyllis Vitolo  
Research Fellow  
PDI Regulatory Affairs



## Jean Claude Marcelin

---

**From:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Sent:** Tuesday, November 13, 2018 1:03 PM  
**To:** Jean Claude Marcelin; Bain, Zeno  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL  
**Attachments:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

I understand that you are frustrated and I'm sorry for the confusion. I received some confirmation from the efficacy team leader:

For the C. diff study (MRID 50667312) the lot number listed throughout the study is Lot No. PDI-0061-LO-1003-150-A. The COA attached (page 45) is for Lot No. PDI-0061-LO-1003-152-A and not for the lot that the study report states was used for testing. The date on the COA for Lot No. PDI-0061-LO-1003-150-A is 6/20/2018 which is after the test date of 5/31. There is not harmony between the stated lot that was tested (150-A) and the COA attached (152-A).

Based on the email chain below I believe that you missed a previous email that was sent on 11/7/18. This email is attached to the response.

Thank you,

Aline

---

**From:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Sent:** Tuesday, November 13, 2018 10:03 AM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>; Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Good morning,

I am withdrawing the PRIA action.

It is very disturbing to me that the Agency could not give me a straight answer regarding a wrong assessment from the efficacy technical screening team. I am not asking the Agency to review the efficacy, all I am asking is for the efficacy technical screening team to confirm they have made a mistake by adding Lot# PDI-0061-LO-1003-150-A - used in *Clostridium difficile* spore study MRID 50667312 in the technical failure. The CoA for Lot# PDI-0061-LO-1003-150-A is clearly dated 5/22/2018 and the efficacy test was performed on 5/31/2018. I cannot comprehend why it is so difficult to confirm it was an oversight from the efficacy technical screening team? I do not want to get the same technical failure when I resubmit the application for review. Our business depends on the Agency to help us put efficacious products on the market, we would never want to deceive the Agency by doing anything illegal. We take pride in our Company's reputation and want to provide all the required documentation the Agency required to put the best product in the market.

Thank you!

Jean Claude Marcelin

SR. MANAGER, REGULATORY AFFAIRS EPA SERVICES  
NICE-PAK PRODUCTS, INC  
PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.



100 PHILIPS PARKWAY  
MONTVALE, NJ 07645  
P 201-746-8922

[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)

pdipdi.com



From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]

Sent: Tuesday, November 13, 2018 7:49 AM

To: Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>; Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

Subject: RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

Thank you for the study but at this time we cannot review it. Even if the C. Diff study was acceptable the base organisms need to be on the label for it to be a hospital disinfectant. C. Diff claims are only allowed on qualified hospital disinfectant products.

With a technical screen there is only one attempt to address all the problems with the studies. The rebuttal that was submitted was not enough to have the efficacy team say the studies pass the technical screen. You will need to resubmit with efficacy data that is appropriate and at that point the C. Diff study can be reevaluated as a part of the new product registration.

Currently we have two courses of action.

1. You can withdraw the action.
2. I can begin the denial process and deny the registration.

Please let me know how you would like to move forward. If I do not have an answer by tomorrow (11/14) at COB I will begin the denial process.

Please let me know if you have any questions or concerns.

Thank you,

Aline

From: Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

Sent: Monday, November 12, 2018 2:15 PM

To: Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>; Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

Subject: RE: Project Flash Wipes MRID Letter 9480-RL

Good morning Bain,

Since I did not get a response, I am attaching the study we submitted with the application to get some clarification why Lot# PDI-0061-LO-1003-150-A - used in *Clostridium difficile* spore study MRID 50667312 was mentioned in the technical failure.

Please let me know as soon as possible.

Thank you!

Jean Claude Marcelin

SR. MANAGER, REGULATORY AFFAIRS EPA SERVICES  
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MONTVALE, NJ 07645  
P 201-746-8922

[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)

pdipdi.com



---

**From:** Jean Claude Marcelin

**Sent:** Wednesday, November 07, 2018 2:30 PM

**To:** 'Heffernan, Aline' <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>

**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Hi Aline,

I am very confused by your response, please take a look at the last paragraph of the technical failure that was sent to us. I believe there was an error on the technical review team regarding *Clostridium difficile*.

The report says:

PDI-0061-LO-1003-150-A was tested for AI concentration 20 days after being used in efficacy study against spores of *Clostridium difficile*.

The efficacy study was performed after the AI analysis was done not 20 days after.

We just would like to know that the Agency agreed the efficacy study was NOT tested for AI concentration 20 days after being used in efficacy study against spores of *Clostridium difficile*.

Thank you!

Jean Claude

---

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]

**Sent:** Wednesday, November 07, 2018 2:17 PM

**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>

**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

For this study a review was not complete. I cannot say if the study was acceptable or unacceptable. If the study was not highlighted in the technical screen failure then the study could have pass the technical screen. There is no guarantee the product would pass the review if one was completed.

The CoA should always be done a reasonable time before any efficacy testing is started. However, I cannot give you any more specific information on the particular study.

Thank you,

Aline

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Wednesday, November 07, 2018 2:08 PM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Hi Aline,

Thank you for your response!

We understand the product needs to be a hospital disinfectant before C. Diff claims can be added. Our concern is, during the technical screening it was stated that: PDI-0061-LO-1003-150-A was tested for AI concentration 20 days after being used in efficacy study against spores of *Clostridium difficile*.

The efficacy study was performed after the AI analysis was done not 20 days after, we just want to clarify that fact because the CoA we submitted with the application is correct. We would like to know that the Agency agreed the efficacy study is acceptable before we withdraw the PRIA action.

Regards,

Jean Claude

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Wednesday, November 07, 2018 1:53 PM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

I spoke with the efficacy team leader and the product needs to be a hospital disinfectant before C. Diff claims can be added. Since the studies for the base organisms for a hospital disinfectant are not acceptable, the product cannot be a hospital disinfectant. Therefore the C. Diff claims cannot be added to the label regardless if the C. Diff study is acceptable.

Please let me know how you would like to move forward, you can withdraw the PRIA action or we can deny it.

Thank you,

Aline

**From:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Sent:** Wednesday, November 07, 2018 11:17 AM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>

Subject: RE: Project Flash Wipes MRID Letter 9480-RL

Hi Aline,

The efficacy team did not comment on the Lot below, can you please tell me why? The study meets the EPA testing requirements, please confirm that the study is acceptable.

**RE: Lot# PDI-0061-LO-1003-150-A - used in *Clostridium difficile* spore study MRID 50667312**

In the memo, EPA has indicated that the AI analysis of Lot **PDI-0061-LO-1003-150-A** was conducted after the efficacy study was performed. Based on PDI's internal review of the study MRID 50667312 and accompanying CoA, we have concluded that the efficacy study was performed after the AI analysis was done. The CoA was issued on 22 May 2016 and the efficacy study followed thereafter on 31 May 2016. Based on this, the study meets the criteria for acceptance as per the Agency's requirements.

Regards,

**Jean Claude Marcelin**

MANAGER, REGULATORY AFFAIRS EPA SERVICES  
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[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)

pdipdi.com



From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]

Sent: Tuesday, November 06, 2018 3:49 PM

To: Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>

Subject: RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

I hope you are doing well. I heard from the efficacy team. The product does not pass the technical screen. The rationale that was submitted did not change the efficacy's team position.

At this time there are two options. You can withdraw the PRIA or the Agency can deny the PRIA action. Because the product failed to adequately respond to the technical screen there is not a way to rebut this decision with additional information. The efficacy team will not review any additional information that you send.

Please let me know if you have any questions or concerns.

Thank you,

Aline

From: Jean Claude Marcelin [<mailto:jmarcelin@pdipdi.com>]

Sent: Tuesday, November 06, 2018 8:38 AM

**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Good morning Aline,

Thank you for the update! Please let me know as soon as you heard from the efficacy team.

Have a great day!

Jean Claude

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Tuesday, November 06, 2018 8:17 AM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean Claude,

The information is currently with the efficacy team. I haven't heard if the product passes the technical screen. I will follow up with the reviewer and the team leader.

Thank you,

Aline

**From:** Jean Claude Marcelin [<mailto:jmarcelin@pdipdi.com>]  
**Sent:** Monday, November 05, 2018 10:07 AM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Good morning Aline,

I hope all is well. Can you please let me know when we may get a response from the EPA regarding the rationale we sent back?

Thank you!

Jean Claude

**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Monday, October 29, 2018 9:54 AM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Bain, Zeno <[Bain.Zeno@epa.gov](mailto:Bain.Zeno@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean,

For a complete response we need the information in writing. I will then send it to the efficacy team and they will decide if that is enough information to pass the technical screen.

To satisfy the efficacy technical screen failure we need a response within 10 business days of receipt of the letter, which was Thursday 10/25. The response should be scientifically valid, detailed and thorough and should be emailed to me. The screen is not something that can be resolved with a phone call, we need an official response in writing. If you have any questions on why it failed please email them to me and I will discuss them with the efficacy reviewer.

Thank you,

Aline

**From:** Jean Claude Marcelin [<mailto:jmarcelin@pdipdi.com>]  
**Sent:** Monday, October 29, 2018 9:48 AM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Hi Aline,

Thank you for your email! We would like to address this issue, is it possible we can give you a call this morning to discuss? We would really to resolve this issue as soon as possible. Please let me know.

Thank you!

**Jean Claude Marcelin**

MANAGER, REGULATORY AFFAIRS EPA SERVICES  
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PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.  
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P 201-746-8922  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
[pdipdi.com](http://pdipdi.com)



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**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Thursday, October 25, 2018 12:20 PM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Cc:** Melissa Louisjuste <[melissa.louisjuste@pdipdi.com](mailto:melissa.louisjuste@pdipdi.com)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean,

I hope you are doing well. I heard from the science reviewers and there was an efficacy failure. Please see the attached technical screen failure letter and efficacy technical screen. Please confirm receipt of this email and let me know if you have any questions or concerns.

Thank you,

Aline

**From:** Jean Claude Marcelin [<mailto:jmarcelin@pdipdi.com>]  
**Sent:** Friday, September 28, 2018 9:23 AM  
**To:** Heffernan, Aline <[heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov)>  
**Cc:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>; Melissa Louisjuste <[melissa.louisjuste@pdipdi.com](mailto:melissa.louisjuste@pdipdi.com)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Good morning Aline,

Thank you for your response regarding that matter! I am looking forward to getting information on Project Flash Wipes from now on. Attached is a pdf copy of the master label. Please let me know if you need anything else.

Thank you and have a wonderful day!

**Jean Claude Marcelin**

**MANAGER, REGULATORY AFFAIRS EPA SERVICES**  
**NICE-PAK PRODUCTS, INC**  
**PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.**  
**100 PHILIPS PARKWAY**  
**MONTVALE, NJ 07845**  
**P 201-746-8922**  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
[pdipdi.com](http://pdipdi.com)



**From:** Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]  
**Sent:** Friday, September 28, 2018 8:04 AM  
**To:** Jean Claude Marcelin <[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)>  
**Subject:** RE: Project Flash Wipes MRID Letter 9480-RL

Jean,

I hope you are doing well. I am the risk manager who is working on your PRIA. I would like to apologize for sending the letter to Delta rather than to you and your company. I'm not sure why the letter was sent to Delta, it clearly says on all the material submitted that you are the point of contact.

In any event, I will send you any information I have on the product. As of now, the product is still in the technical screen. As soon as I hear from the science reviewers if the product has passed or failed the technical screen I will let you know.

I have not sent any emails to Delta about this product.

Can you please send me a PDF copy of the label?

Thank you,

Aline

\*\*\*\*\*

Aline Heffernan  
Regulatory Management Branch 1  
Antimicrobials Division  
Office of Pesticide Programs

703-347-8602

**From:** Bain, Zeno  
**Sent:** Thursday, September 27, 2018 5:09 PM  
**To:** Heffernan, Aline <heffernan.aline@epa.gov>  
**Subject:** FW: Project Flash Wipes MRID Letter

**From:** Jean Claude Marcelin [mailto: ]  
**Sent:** Thursday, September 27, 2018 4:41 PM  
**To:** Bain, Zeno <Bain.Zeno@epa.gov>  
**Subject:** FW: Project Flash Wipes MRID Letter

Hello Bain,

Please do not send any correspondence regarding this application to Delta. We thought it was very clear the cover letter that was included with the application came from me not from Delta. Delta is NOT our agent for this application, we at PDII submitted that application to the agency NOT Delta.

Thank you!

**Jean Claude Marcelin**

MANAGER, REGULATORY AFFAIRS EPA SERVICES  
NICE-PAK PRODUCTS, INC  
PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.  
100 PHILIPS PARKWAY  
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[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
[pdipdi.com](http://pdipdi.com)



**From:** Jaqueline Sumski [mailto:jsumski@delta-ac.com]  
**Sent:** Thursday, September 27, 2018 3:06 PM  
**To:** Jean Claude Marcelin <jmarcelin@pdipdi.com>  
**Cc:** Melissa Louisjuste <melissa.louisjuste@pdipdi.com>  
**Subject:** Project Flash Wipes MRID Letter

Jean Claude,

Please find attached a copy of the MRID assignment letter Delta received in the mail.

Best Regards,

*Jaqueline Sumski*

Delta Analytical Corporation  
[jsumski@delta-ac.com](mailto:jsumski@delta-ac.com)  
12510 Prosperity Drive, Suite 160  
Silver Spring, MD 20904  
P: 301 680-7971  
F: 301 680-7975





INTERVENTIONAL CARE

PATIENT CARE

ENVIRONMENT OF CARE

NOV 14 2018  
10:14 AM  
PDI

Aline Heffernan / Zeno Bain  
U.S. Environmental Protection Agency  
Regulatory Management Branch I  
Antimicrobial Division (7510P)  
Office of Pesticide Programs

November 14, 2018

Subject: Technical Screen Failure – Follow-up on *C. difficile* Spores MRID 50667312  
Product Name: Project Flash Wipes  
EPA File Symbol: 9480-RL  
Application Date: 08/22/18  
Decision Number: 543820 – Follow-up to Memo Dated November 13, 2018

Dear Ms. Heffernan and Mr. Bain,

Based on email correspondence dated November 13, 2018 related to Project Flash Wipes MRID Letter 9480-RL, PDI would like to specifically address the confusion in regards to the Project Flash Wipes test product lots (PDI-0061-1003-150-A, -151-A, and -152-A). The confusion seems to be related to the Certificates of Analysis (CoA) used in the three (3) efficacy studies performed against *Clostridium difficile* spores (Vol 12 - MRID 50667312) and the CoA's for the two (2) lots used in the Hepatitis C virus study (Vol 10 - MRID 50667310).

PDI understands that the PRIA action has been withdrawn for this submission; however, the efficacy data generated in each of the three (3) required *Clostridium difficile* spores studies contained in Volume 12, MRID 50667312 were initiated after the CoA's were generated and are valid.

Please refer to the following table that outlines the specific information reported in each of the four Project Flash Wipe studies submitted as Volume 10 and Volume 12 that support claims against *Clostridium difficile* spores and the Hepatitis C virus.

### Project Flash Wipes 9480-RL

Organism & MRID #	Lot #	Efficacy Study #	Efficacy Study Test Start Date	CoA #	CoA AI Analysis Test Date	CoA LCL AI% Result
<i>Clostridium difficile</i> spores MRID 50667312  (Volume 12)	PDI-0061-1003-150-A	735-294	05/31/18 (page 9)	COC-18-B-103	05/22/18 (page 45)	3.82%
	PDI-0061-1003-151-A	735-295	06/07/18 (page 9)	COC-18-B-104	05/22/18 (page 45)	3.84%
	PDI-0061-1003-152-A	735-296	06/08/18 (page 9)	COC-18-B-105	05/22/18 (page 45)	3.83%
Hepatitis C – (Bovine Viral Diarrhea Virus)  MRID 50667310  (Volume 10)	PDI-0061-1003-150-A	735-297	06/21/18 (page 8)	COC-18-B-131	06/20/18 (page 34)	3.69%
	PDI-0061-1003-151-A			COC-18-B-132	06/20/18 (page 33)	3.68%
Comments:						
1) The %AI's for Lot numbers ending in -150-A, 151-A and -152-A were initially assayed on 5/22/18 before the <i>C. difficile</i> efficacy studies were conducted on 05/31/18, 06/07/18 and 06/08/18, respectively.						
2) The %AI's for the same two Lots, -150-A and -151-A, were then re-assayed on 06/20/18 before the Hepatitis C viral study that was conducted on 06/21/18.						

Based on the above, each individual lot was assayed prior to the initiation of each efficacy study and meets the regulatory criteria for valid efficacy studies.



INTERVENTIONAL CARE

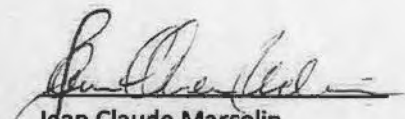
PATIENT CARE

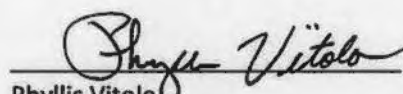
ENVIRONMENT OF CARE

PDI requests that the Efficacy Team technical reviewer consider these data to gain concurrence on the validity of the three *Clostridium difficile* spore studies. With this concurrence, we would like to re-submit these three studies in the future submission to support the *C. difficile* spore claim for Project Flash Wipes.

Thank you for your time and consideration.

Sincerely,

  
Jean Claude Marcelin  
Senior Manager  
PDI Regulatory Affairs

  
Phyllis Vitolo  
Research Fellow  
PDI Regulatory Affairs

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/3/19

Experts In-Processing Signature: [Signature] Date 4/4/19 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date                     

EPA Reg. Number: <u>9480-RA</u>		EPA Receipt Date: <u>4/3/19</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

Documentation: PASS

↳ All required documents are complete

Inerts PASS

↳ Inerts approved for Non-Food Use.

11/3 PASS

↳ MRID 508288

Status: PASS

↳ 11/16/19



\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

##### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

##### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



## A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAi in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAi)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.1550	Product Identity & Composition	x		
830.1600	Description of materials used to produce the product	x		
830.1650	Description of formulation process	x		
830.1670	Discussion on the formation of impurities	x		
830.1700	Preliminary analysis	x		
830.1750	Certified limits (158.345)	x		
830.1800	Enforcement analytical method	x		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.6302	Color	x		
830.6303	Physical State	x		
830.6304	Odor	x		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	x		
830.6315	Flammability	x		
830.6316	Explosibility	x		
830.6317	Storage stability*	/		
830.6319	Miscibility	x		
830.6320	Corrosion Characteristics*	x		
830.6321	Dielectric Breakdown Voltage	x		
830.7000	pH	x		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	x		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	x		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

\*May not be included with initial application

## A540 – Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below),
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		X		
830.1200	Acute Dermal (LD50)		X		
830.1300	Acute Inhalation (LC50)		X		
830.2400	Acute Eye Irritation		X		
830.2500	Acute Dermal Irritation		X		
830.2600	Dermal Sensitization		X		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 3, 2019

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-549617  
EPA File Symbol or Registration Number: 9480-RA  
Product Name: PROJECT FLASH WIPES  
EPA Receipt Date: 03-Apr-2019  
EPA Company Number: 9480  
Company Name: PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.

JEAN CLAUDE MARCELIN  
PDI, INC  
PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.  
400 CHESTNUT RIDGE ROAD  
WOODCLIFF LAKE, NJ 07677

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

New end use product;FIFRA §2(mm) uses only;up to 25 public health organisms;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

  
Front End Processing Staff  
Information Technology & Resources Management Division

**Melissa Louisjuste**

---

**From:** notification@pay.gov  
**Sent:** Friday, March 15, 2019 4:32 PM  
**To:** Melissa Louisjuste  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees



An official email of the United States government



Your payment has been submitted to Pay.gov and the details are below. To confirm that the payment processed as expected, you may refer to your bank statement on the scheduled payment date. If you have any questions or wish to cancel this payment, you will need to contact the agency you paid at your earliest convenience.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 26G4DDSR

Agency Tracking ID: 75703436896

Account Holder Name: Professional Disposables International Inc.

Transaction Type: ACH Debit

Transaction Amount: \$5,107.00

Payment Date: 03/18/2019

Account Type: Business Checking

Routing Number: 021306822

Account Number: \*\*\*\*\*9754

Transaction Date: 03/15/2019 04:31:56 PM EDT

Total Payments Scheduled: 1

Frequency: OneTime

Registration Number:

Company Name: Professional Disposables

Company Number: 9480

Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



Pay.gov is a program of the U.S. Department of the Treasury, Bureau of the Fiscal Service

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address  <b>Professional Disposables International, Inc. (PDI)</b> 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677	EPA File Symbol/Registration Number <b>9480-</b>
	Product Name <b>Project Flash Wipes</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>03/20/2019</b>

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

**Hydrogen Peroxide 35%**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).


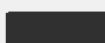

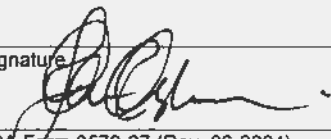
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Hydrogen Peroxide 35%		 
Signature 	Name and Title <b>Jean Claude Marcelin/Sr. Manager</b>	Date <b>03/20/2019</b>

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
 Copy 2 - Applicant copy



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Professional Disposables International, Inc. (PDI), 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677	EPA Registration Number/File Symbol 9480-
Active Ingredient(s) and/or representative test compound(s) Hydrogen Peroxide 35%	Date 03/20/19
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Domestic indoor	Product Name Project Flash Wipes

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 03/20/19	Typed or Printed Name and Title Jean Claude Marcelin, Sr. Regulatory Affairs Manager
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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 9480-	2. EPA Product Manager Zeno Bain	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Project Flash Wipes	PM # PM 33	
5. Name and Address of Applicant (Include ZIP Code) Professional Disposables International, Inc. (PDI) 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677  <input checked="" type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Application for Registration of Project Flash Wipes; PRIA Fee Category A540 (receipt attached); Decision time 5 months; Fee: \$5,107; Contact name: Jean Claude Marcelin, email: jmarcelin@pdipdi.com

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. approx. 0.40 oz.	No. per container 50
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 - 1000 towlettes	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Adhesive label applied to front and back	

## Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jean Claude Marcelin	Title Sr. Manager, Regulatory Affairs EPA Services	Telephone No. (Include Area Code) 201-746-8922
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature 	3. Title Sr. Manager, Regulatory Affairs EPA Services	
Typed Name Jean Claude Marcelin	5. Date 03/20/19	